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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.

2. The relationship between the Federal Register and Code of Federal Regulations.

3. The important elements of typical Federal Register documents.

4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, July 17, 2007
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

Contents

Federal Register

Vol. 72, No. 121

Monday, June 25, 2007

Separate Parts In This Issue

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, reminders, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 72, No. 121
Monday, June 25, 2007

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2007–0051]

Mexican Fruit Fly; Removal of Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Mexican fruit fly regulations by removing a portion of Webb County, TX, from the list of quarantined areas and by removing restrictions on the interstate movement of regulated articles from this area. This action is necessary to relieve restrictions that are no longer needed to prevent the spread of the Mexican fruit fly into noninfested areas of the United States. We have determined that the Mexican fruit fly has been eradicated from this portion of Webb County, TX, and that the quarantine and restrictions are no longer necessary.

DATES: This interim rule was effective June 18, 2007. We will consider all comments that we receive on or before August 24, 2007.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov,* select ''Animal and Plant Health Inspection Service'' from the agency drop-down menu, then click ''Submit.'' In the Docket ID column, select APHIS–2007–0051 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link.
- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2007–0051, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2007–0051.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Wayne Burnett, Domestic Coordinator, Fruit Fly Exclusion and Detection, PPQ, APHIS, 4700 River Road Unit 36, Riverdale, MD 20737–1231; (301) 734–4387.

SUPPLEMENTARY INFORMATION:

Background

The Mexican fruit fly (*Anastrepha ludens*) is a destructive pest of citrus and many other types of fruit. The short life cycle of the Mexican fruit fly allows rapid development of serious outbreaks that can cause severe economic losses in commercial citrus-producing areas.

The Mexican fruit fly regulations, contained in 7 CFR 301.64 through 301.64–10 (referred to below as the regulations), were established to prevent the spread of the Mexican fruit fly to noninfested areas of the United States. The regulations impose restrictions on the interstate movement of regulated articles from quarantined areas.

In an interim rule effective and published in the **Federal Register** on May 18, 2007 (72 FR 27949–27951, Docket No. APHIS–2007–0051), we quarantined a portion of Webb County, TX, and restricted the interstate movement of regulated articles from the quarantined area.

Based on trapping surveys conducted by inspectors of Texas State and county agencies and by inspectors of the Animal and Plant Health Inspection Service, we have determined that the Mexican fruit fly has been eradicated from the quarantined portion of Webb County. The last finding of Mexican fruit fly in this quarantined area was March 6, 2007.

Since then, no evidence of Mexican fruit fly infestation has been found in this area. Based on our experience, we have determined that sufficient time has passed without finding additional flies or other evidence of infestation to conclude that the Mexican fruit fly no longer exists in Webb County, TX. Therefore, we are removing the entry for this county from the list of quarantined areas in § 301.64–3(c).

Immediate Action

Immediate action is warranted to relieve restrictions that are no longer necessary. A portion of Webb County, TX, was quarantined due to the possibility that the Mexican fruit fly could spread from this area to noninfested areas of the United States. Since we have concluded that the Mexican fruit fly no longer exists in this county, immediate action is warranted to remove the quarantine on Webb County, TX, and to relieve the restrictions on the interstate movement of regulated articles from this area. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This action amends the Mexican fruit fly regulations by removing a portion of Webb County, TX, from the list of quarantined areas.

The Regulatory Flexibility Act requires that agencies consider the economic impact of their rules on small entities. The Small Business Administration (SBA) has established size standards for determining which economic entities meet the definition of a small firm. The SBA classifies entities that would normally be affected by a quarantine for the Mexican fruit fly, growers of oranges (NAICS category 111310), citrus (except orange) groves (NAICS category 111320), apple orchards (NAICS category 111331), and other non-citrus farming (NAICS category 111339), as small businesses if their annual receipts are $750,000 or less. Any infestation by Mexican fruit fly could result in an increase in producer costs for pesticides and their application and a reduction in production and revenue. However, according to the 2002 Census of Agriculture, there were no commercial farms growing these commodities in Webb County, TX.

County records indicate there are approximately 1 airport, 4 bus terminals, 2 cargo freight forwarders, 2 distributors, 1 food bank, 2 nurseries, and 128 fruit sellers within the area that may be affected by this rule.

We expect that any small entities located within the area that sell regulated articles do so primarily for local intrastate, not interstate, movement, so the effect, if any, of this rule on these entities appears to be minimal. The effect on any small entities that may move regulated articles interstate has been minimized by the availability of various treatments that, in most cases, allow these small entities to move regulated articles interstate with very little additional cost. Thus, just as the previous interim rule establishing the quarantined area in Webb County, TX, had little effect on the small entities in the area, the lifting of the quarantine in the current interim rule will also have little effect.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

■ Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

§ 301.64–3 [Amended]

■ 2. In § 301.64–3, paragraph (c) is amended by removing, under the heading ''TEXAS'', the entry for Webb County.

Done in Washington, DC, this 18th day of June 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–12231 Filed 6–22–07; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL RESERVE SYSTEM

12 CFR Part 229

[Regulation CC; Docket No. R–1289]

Availability of Funds and Collection of Checks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; technical amendment.

SUMMARY: The Board of Governors is amending appendix A of Regulation CC to delete the reference to the head office of the Federal Reserve Bank of San Francisco and reassign the Federal Reserve routing symbols currently listed under that office to the Los Angeles branch office of the Federal Reserve Bank of San Francisco. These amendments will ensure that the information in appendix A accurately describes the actual structure of check processing operations within the Federal Reserve System.

DATES: The final rule will become effective on August 18, 2007.

FOR FURTHER INFORMATION CONTACT: Jack K. Walton II, Associate Director (202/452–2660), or Joseph P. Baressi, Financial Services Project Leader (202/452–3959), Division of Reserve Bank Operations and Payment Systems; or Adrianne G. Threatt, Counsel (202/452–3554), Legal Division. For users of Telecommunications Devices for the Deaf (TDD) only, contact 202/263–4869.

SUPPLEMENTARY INFORMATION: Regulation CC establishes the maximum period a depositary bank may wait between receiving a deposit and making the deposited funds available for withdrawal.[1] A depositary bank generally must provide faster availability for funds deposited by a local check than by a nonlocal check. A check drawn on a bank is considered local if it is payable by or at a bank located in the same Federal Reserve check processing region as the depositary bank. A check drawn on a nonbank is considered local if it is payable through a bank located in the same Federal Reserve check processing region as the depositary bank. Checks that do not meet the requirements for local checks are considered nonlocal.

Appendix A to Regulation CC contains a routing number guide that assists banks in identifying local and nonlocal banks and thereby determining the maximum permissible hold periods for most deposited checks. The appendix includes a list of each Federal Reserve check processing office and the first four digits of the routing number, known as the Federal Reserve routing symbol, of each bank that is served by that office for check processing purposes. Banks whose Federal Reserve routing symbols are grouped under the same office are in the same check processing region and thus are local to one another.

[1] For purposes of Regulation CC, the term ''bank'' refers to any depository institution, including commercial banks, savings institutions, and credit unions.

As explained in the Board's final rule published in the **Federal Register** on May 18, 2007, the Federal Reserve Banks have decided to restructure their check processing services by reducing further the number of locations at which they process checks.[2] The Board issues separate final rules amending appendix A for each phase of the restructuring, and the amendments set forth in this notice are such final rules.[3]

As part of the restructuring process, the head office of the Federal Reserve Bank of San Francisco will cease processing checks on August 18, 2007. As of that date, banks with routing symbols currently assigned to the San Francisco head office for check processing purposes will be reassigned to the San Francisco Reserve Bank's Los Angeles branch office. As a result of this change, some checks that are drawn on and deposited at banks located in the affected check processing regions and that currently are nonlocal checks will become local checks subject to faster availability schedules.

To assist banks in identifying local and nonlocal banks, the Board accordingly is amending the lists of routing symbols assigned to Twelfth District check processing offices to conform to the transfer of operations from the San Francisco head office to the Los Angeles branch office. To coincide with the effective date of the underlying check processing changes, the amendments are effective August 18, 2007. The Board is providing advance notice of these amendments to give affected banks ample time to make any needed processing changes. The advance notice also will enable affected banks to amend their availability schedules and related disclosures, if necessary, and provide their customers with notice of these changes.[4] The Federal Reserve routing symbols assigned to all other Federal Reserve branches and offices will remain the same at this time. The Board of Governors, however, intends to issue a similar notice at least sixty days prior to the elimination of check processing operations at the Helena branch office of the Federal Reserve Bank of Minneapolis, as described in the May 2007 **Federal Register** document.

Administrative Procedure Act

The Board has not followed the provisions of 5 U.S.C. 553(b) relating to notice and public participation in connection with the adoption of this final rule. The revisions to the appendix are technical in nature, and the routing symbol revisions are required by the statutory and regulatory definitions of ''check-processing region.'' Because there is no substantive change on which to seek public input, the Board has determined that the section 553(b) notice and comment procedures are unnecessary.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR part 1320 Appendix A.1), the Board has reviewed the final rule under authority delegated to the Board by the Office of Management and Budget. This technical amendment to appendix A of Regulation CC will delete the reference to the head office of the Federal Reserve Bank of San Francisco and reassign the routing symbols listed under that office to the Los Angeles branch office of the Federal Reserve Bank of San Francisco. The depository institutions that are located in the affected check processing regions and that include the routing numbers in their disclosure statements would be required to notify customers of the resulting change in availability under § 229.18(e). However, because all paperwork collection procedures associated with Regulation CC already are in place, the Board anticipates that no additional burden will be imposed as a result of this rulemaking.

List of Subjects in 12 CFR Part 229

Banks, Banking, Reporting and recordkeeping requirements.

Authority and Issuance

■ For the reasons set forth in the preamble, the Board is amending 12 CFR part 229 to read as follows:

PART 229—AVAILABILITY OF FUNDS AND COLLECTION OF CHECKS (REGULATION CC)

■ 1. The authority citation for part 229 continues to read as follows:

Authority: 12 U.S.C. 4001–4010, 12 U.S.C. 5001–5018.

■ 2. The Twelfth District routing symbol list in appendix A is revised to read as follows:

Appendix A to PART 229—Routing Number Guide to Next-Day Availability Checks and Local Checks

* * * * *

Twelfth Federal Reserve District

[Federal Reserve Bank of San Francisco]

Los Angeles Branch

1210	3210
1211	3211
1212	3212
1213	3213
1220	3220
1221	3221
1222	3222
1223	3223
1224	3224

Seattle Branch

1230	3230
1231	3231
1232	3232
1233	3233
1250	3250
1251	3251
1252	3252

* * * * *

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, June 20, 2007.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E7–12194 Filed 6–22–07; 8:45 am]

BILLING CODE 6210–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 115

RIN 3245–AF39

Surety Bond Guarantee Program-Preferred Surety Qualification, Increased Guarantee for Veteran and Service-Disabled Veteran-Owned Business, Deadline for Payment of Guarantee Fees, Denial of Liability, and Technical Amendments

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Final rule.

SUMMARY: On September 26, 2006, SBA published a proposed rule in the **Federal Register** addressing six changes to the SBA Surety Bond Guarantee (SBG) Program in order to improve operation of the SBG program and make it easier for sureties and small business concerns to participate in the program. Specifically, this rules makes the following amendments to the program: (1) Gives effect to the statutory reduction in the frequency of audits required of Preferred Surety Bond (PSB) Sureties; (2) obligates SBA to guarantee 90 percent of the loss incurred by a Prior Approval Surety on bonds issued

[2] *See* 72 FR 27951, May 18, 2007.

[3] In addition to the general advance notice of future amendments provided by the Board, and the Board's notices of final amendments, the Reserve Banks strive to inform affected depository institutions of the exact date of each office transition at least 120 days in advance. The Reserve Banks' communications to affected depository institutions are available at *http://www.frbservices.org.*

[4] Section 229.18(e) of Regulation CC requires that banks notify account holders who are consumers within 30 days after implementing a change that improves the availability of funds.

on behalf of small businesses owned and controlled by veterans, and Service-disabled veterans; (3) imposes a 60-day deadline for the submission of surety fees to SBA; (4) allows PSB Sureties to charge premiums in accordance with applicable state ceilings, as presently permitted under the Prior Approval Program; (5) deletes the existing reference to the expiration of the PSB Program; and (6) allows Affiliates of a PSB Surety to participate in the Prior Approval Program.

DATES: This rule is effective July 25, 2007.

FOR FURTHER INFORMATION CONTACT: Frank Lalumiere, Director, Office of Surety Guarantees, (202) 205–6540; *Frank.Lalumiere@sba.gov*.

SUPPLEMENTARY INFORMATION:

SBA can guarantee bonds for contracts up to $2 million, covering bid, performance and payment bonds for small and emerging contractors who cannot obtain surety bonds through regular commercial channels. SBA's guarantee gives sureties an incentive to provide bonding for small businesses and thereby strengthens their ability to obtain bonding and greater access to contracting opportunities.

Section 411(g)(3) of the Small Business Investment Act of 1958 (the Act) formerly required PSB Sureties to be audited every year. 15 U.S.C. 694b(g)(3). As amended by Public Law 108–447, Div. K. Section 203, the Small Business Reauthorization and Manufacturing Assistance Act of 2004, the Act now requires audits to be made at least once every 3 years. This final rule implements this statutory requirement.

In relevant part, Section 4(b)(1) of the Small Business Act provides that SBA ''shall give special consideration to veterans of the Armed Forces of the United States and their survivors and dependents.'' 15 U.S.C. 633(b)(1). This final rule encourages the issuance of bonds on behalf of small business concerns owned and controlled by veterans and Service-disabled veterans, by guaranteeing to pay 90 percent of a Prior Approval Program Surety's loss. This guaranty affords such concerns more opportunity to obtain contracts generally.

Section 411(h) of the Small Business Investment Act mandates the operation of the program ''on a prudent and economically justifiable basis'' and authorizes SBA to impose fees on both small business concerns and sureties, ''to be payable at such time as may be determined by [SBA].'' Accordingly, this final rule establishes a clear deadline for a Prior Approval Surety's payment of the guarantee fees owed to SBA in order to maintain SBA's guarantee.

The final rule also allows PSB Program Sureties to charge no more than the premium rates permitted under applicable State law, as Prior Approval Sureties are already allowed. The initial regulations for the PSB program specified that the premium rates charged by PSB Sureties could not exceed the Surety Association of America's advisory premium rates in effect on August 1, 1987. SAA discontinued its rate setting function shortly after promulgating the 1987 rates, and participating surety companies have been obligated to use the 1987 SAA rates for the past 18 years despite economic and market place changes. This change puts the Preferred and Prior Approval Programs on the same footing by relying on the individual State oversight bodies for setting fee rates.

From its creation in 1988 until 2004, the PSB program was a pilot program, subject to automatic termination in the absence of affirmative Congressional action. Now that the PSB program has been made permanent, the present regulation that speaks of the termination of the program has been removed.

Finally, pursuant to this rule Affiliates of PSB Sureties are no longer barred from participation in the Prior Approval program. The term ''Affiliate'' is defined in 13 CFR part 121, but in the context of the present discussion it means a relationship in which one Surety owns or otherwise controls another Surety, or in which two or more Sureties are commonly owned by, or under common control with, a third party. A series of mergers and acquisitions in the surety industry in recent years had caused Sureties previously eligible to participate in the Prior Approval Program to become Affiliates of PSB Sureties and lose their eligibility. This final amendment should encourage increased participation in the Prior Approval Program by otherwise qualified Sureties that are Affiliates of PSB Sureties.

Discussion of Public Comments

SBA received five public comments on the proposed rule, three from associations and two from individual surety companies. Each commenter supported the proposed changes, with two exceptions.

Four commenters recommended removal of the proposed language in § 115.19, Denial of Liability, that would allow SBA to deny bond liability as a result of the failure of a surety company to pay the required surety fee. In general, the commenters stated that such a requirement would weaken the SBA/Surety Industry partnership that is designed to assist small businesses. While SBA values its partners in the surety industry, the Agency has a fiduciary responsibility to ensure timely payment of guaranty fees in order to honor its guaranty. Accordingly, the language in the proposed rule regarding the denial of bond liability if the surety fee is not paid within 60 days is retained. The proposed rule also included a provision that the guaranty can be reinstated if a valid reason for the delinquent payment of guaranty fee is provided and the contract is not in default. This language is also retained in the final rule.

Three commenters expressed concern with the proposed 45 days fee payment requirement. One commenter requested clarification of when the 45-day period begins. A few commenters said it would be difficult to remit payment within 45 days, in part because many sureties do not receive payment on the final bond premium until 45 days after the bond is issued, and to require payment before collection on the premium is unduly punitive. In consideration of these comments, in this final rule, SBA has amended the proposed rule. First, the proposed 45-day period cited in § 115.32 is increased to 60 days. SBA believes that the additional 15 days will provide time for a surety company agent to provide the surety company with sufficient information for the surety company to make payment. Second, the same section is also revised to specify that payment is required within 60 days following SBA approval of the Prior Approval Payment or Performance Bond on the SBA Form 990, Guarantee Agreement.

One commenter also suggested that the agency should extend the 10-day deadline for PSB sureties to submit the executed bond to SBA to a 15-day deadline. SBA did not propose to amend this particular requirement, and it will be considered among other changes in a future amendment.

Compliance With Executive Orders 12866, 12988, and 13132, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Compliance With Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule constitutes a significant regulatory action for purposes of Executive Order 12866, thereby necessitating a regulatory impact analysis. SBA

published this analysis in the Proposed Rule. The agency did not receive any comments addressing the analysis and is not aware of any additional information that would require revision of its initial conclusions.

Compliance With Executive Order 12988

This action meets applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Compliance With Executive Order 13132

For purpose of E.O. 13132, the SBA has determined that the rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, for the purpose of Executive Order 13132, SBA determines that this final rule has no federalism implications warranting preparation of a federalism assessment.

Compliance With Paperwork Reduction Act, 44 U.S.C. Ch. 35

SBA has determined that this final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act, 44 U.S.C., Chapter 35.

Compliance With the Regulatory Flexibility Act, 5 U.S.C. 601–612

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, small non-profit enterprises, and small local governments. Pursuant to the RFA, when an agency issues a rulemaking, the agency must prepare a regulatory flexibility analysis which describes the impact of the rule on small entities. However, Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities. Within the meaning of RFA, SBA certifies that this rule will not have a significant economic impact on a substantial number of small entities. Consequently, this rule doe not meet the substantial number of small businesses criterion anticipated by the Regulatory Flexibility Act.

There are about a dozen Sureties that participate in the SBA program, and this rule does not impose any additional cost or any significant burden on them. Allowing PSB Sureties to charge the highest premium rates permitted by applicable State law raises the possibility of an economic impact on those contractors that now receive their bonding from PSB Sureties, but out of 843 contractors participating in the SBA program in FY2005, about 143 were bonded by PSB Sureties. Prior Approval Sureties are already allowed to charge the premium rates permitted by the individual State law, so the economic effect, if any, of this final rule would be to subject approximately 17 percent of the contractors in the SBA program to the risk that they might have to pay the same premium rates that their fellow participating contractors must pay. No public comments were received in response to the RFA analysis provided in the proposed rule.

List of Subjects in 13 CFR Part 115

Claims, Reporting and recordkeeping requirements, Small businesses, Surety bonds.

■ For the reasons stated in the preamble, the Small Business Administration amends 13 CFR part 115 as follows:

PART 115—SURETY BOND GUARANTEE

■ 1. The authority citation for part 115 is revised to read as follows:

Authority: 5 U.S.C. app. 3; 15 U.S.C. 687b, 687c, 694a, 694b note, Pub. L. 106–554; Pub. L. 108–447, Div K, § 203.

■ 2. Amend § 115.10 by adding the following definitions in alphabetical order.

§ 115.10 Definitions.

* * * * *

Service-Disabled Veteran means a veteran with a disability that is service-connected, as defined in Section 101(16) of Title 38, United States Code.

Small Business Owned and Controlled by Service-Disabled Veterans means:

(1) A Small Concern of which not less than 51 percent is owned by one or more Service-Disabled Veterans; or a publicly-owned Small concern of which not less than 51 percent of the stock is owned by one or more Service-Disabled Veterans; and

(2) The management and daily business operations of which are controlled by one or more Service-Disabled Veterans, or in the case of a Service-Disabled Veteran with permanent and severe disability, the spouse or permanent caregiver of such Veteran.

Small Business Owned and Controlled by Veterans means:

(1) A Small Concern of which not less than 51 percent is owned by one or more Veterans; or a publicly-owned Small Concern of which not less than 51 percent of the stock is owned by one or more Veterans; and

(2) The management and daily business operations of which are controlled by one or more Veterans.

* * * * *

Veteran has the meaning given the term in Section 101(2) of Title 38, United States Code.

■ 3. Revise § 115.19(g) to read as follows:

§ 115.19 Denial of liability.

* * * * *

(g) Delinquent fees. The Surety has not remitted to SBA the Principal's payment for the full amount of the guarantee fee within the time period required under § 115.30(d) for Prior Approval Sureties or § 115.66 for PSB Sureties, or has not made timely payment of the Surety's fee within the time period required by § 115.32(c). SBA may reinstate the guarantee upon showing that the contract is not in default and that a valid reason exists why a timely remittance or payment was not made.

* * * * *

■ 4. Revise § 115.21(a)(2) to read as follows:

§ 115.21 Audits and investigations.

(a) * * *

(1) * * *

(2) *Frequency of PSB Audits.* Each PSB Surety is subject to an audit at least once every 3 years by examiners selected and approved by SBA.

* * * * *

■ 5. Revise § 115.31(a)(2) to read as follows:

§ 115.31 Guarantee percentage.

(a) * * *

(1) * * *

(2) The bond was issued on behalf of a small business owned and controlled by socially and economically disadvantaged individuals, on behalf of a qualified HUBZone small business concern, or on behalf of a small business owned and controlled by veterans or a small business owned and controlled by Service-disabled veterans.

* * * * *

■ 6. Revise § 115.32 (c) and (d)(2) to read as follows:

§ 115.32 Fees and premiums.

* * * * *

(c) *SBA charge to Surety.* SBA does not charge Sureties application or Bid Bond guarantee fees. Subject to

§ 115.18(a)(4), the Surety must pay SBA a guarantee fee on each guaranteed bond (other than a Bid Bond) within 60 calendar days after SBA's approval of the Prior Approval Payment or Performance Bond on the SBA Form 990, Guarantee Agreement. The fee is a certain percentage of the bond premium determined by SBA and published in Notices in the **Federal Register** from time to time. The fee is rounded to the nearest dollar. SBA does not receive any portion of a Surety's non-premium charges. See paragraph (d) of this section for additional requirements when the Contract or bond amount changes.

(d) * * *

(1) * * *

(2) *Increases; fees.* Notification of increases in the Contract or bond amount under this paragraph (d) must be accompanied by the Principal's check for the increase in the Principal's guarantee fee computed on the increase in the Contract amount. If the increase in the Principal's fee is less than $40, no payment is due until the total amount of increases in the Principal's fee equals or exceeds $40. The Surety's check for payment of the increase in the Surety's guarantee fee, computed on the increase in the bond Premium, must be submitted to SBA within 60 calendar days of SBA's approval of the supplemental Prior Approval Agreement, unless the amount of such increased guarantee fee is less than $40. When the total amount of increase in the guarantee fee equals or exceeds $40, the Surety's check must be submitted to SBA within 60 calendar days.

* * * * *

■ 7. Revise § 115.60(a)(2) to read as follows:

§ 115.60 Selection and admission of PSB Sureties.

(a) * * *

(1) * * *

(2) An agreement that the Surety will neither charge a bond premium in excess of that authorized by the appropriate State insurance department, nor impose any non-premium fee unless such fee is permitted by applicable State law and approved by SBA.

* * * * *

§ 115.61 [Removed & Reserved]

■ 8. Remove and reserve § 115.61.

■ 9. Revise § 115.62 to read as follows:

§ 115.62 Prohibition on participation in Prior Approval program.

A PSB Surety is not eligible to submit applications under subpart B of this part. This prohibition does not extend to an Affiliate, as defined in 13 CFR § 121.103, of a PSB Surety that is not itself a PSB Surety provided that the relationship between the PSB Surety and the Affiliate has been fully disclosed to SBA and that such Affiliate has been approved by SBA to participate as a Prior Approval Surety pursuant to § 115.11.

Steven C. Preston,

Administrator.

[FR Doc. 07–2983 Filed 6–22–07; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9332]

RIN 1545–BG00

Exclusions From Gross Income of Foreign Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations under section 883(a) and (c) of the Internal Revenue Code (Code), relating to the exclusion from gross income of income derived by certain foreign corporations engaged in the international operation of ships or aircraft. These regulations revise § 1.883–3 of the final regulations, relating to the eligibility of controlled foreign corporations for the exclusion under section 883, following the repeal of section 954(a)(4) and (f) (foreign base company shipping provisions) by section 415 of the American Jobs Creation Act of 2004. In addition, these regulations provide certain additional guidance under section 883(a) and (c), including for foreign corporations that are organized in countries providing an exemption from taxation for certain shipping and air transport income solely through an income tax convention. The text of these temporary regulations also serves as the text of the proposed regulations (REG–138707–06) set forth in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on June 25, 2007.

Applicability Date: For dates of applicability, see § 1.883–5T.

FOR FURTHER INFORMATION CONTACT: Patricia A. Bray, at (202) 622–3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collections of information contained in these regulations has been reviewed, and pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–1667. Responses to these collections of information are mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

For further information concerning these collections of information, where to submit comments on the collections of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referencing notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register**.

Books and records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

1. Section 883 and the Final Regulations

Sections 883(a)(1) and (a)(2) of the Code generally provide that income from the international operation of ships or aircraft derived by a foreign corporation will be excluded from gross income and exempt from U.S. taxation if the foreign country in which the corporation is organized grants an equivalent exemption to corporations organized in the United States. Section 883(c)(1) provides that a foreign corporation cannot qualify for the section 883(a) exemption if 50 percent or more of the value of its stock is owned by individuals who are not residents of a country that grants an equivalent exemption to U.S. corporations. However, under section 883(c)(2), section 883(c)(1) does not apply to a foreign corporation that is a controlled foreign corporation as defined in section 957(a)(CFC). In addition, under section 883(c)(3), section 883(c)(1) does not apply to a foreign corporation whose stock is primarily and regularly traded on an established securities market in the

United States or in a foreign country that grants an equivalent exemption to U.S. corporations.

On August 26, 2003, the IRS and the Treasury Department issued final regulations under section 883 in TD 9087 (68 FR 51394). The final regulations provide, in general, that a foreign corporation organized in a qualified foreign country and engaged in the international operation of ships or aircraft may exclude qualified income from gross income for purposes of U.S. Federal income taxation provided that the corporation can satisfy certain ownership and related substantiation and reporting requirements. A foreign corporation that meets these requirements is a ''qualified foreign corporation.'' A foreign country that grants U.S. corporations an equivalent exemption from gross income is a ''qualified foreign country.'' The final regulations also provide definitions of the terms ''qualified income'' and ''equivalent exemption.'' In addition, the final regulations specify how a foreign corporation can satisfy the ownership and related substantiation and reporting requirements, and the information that the foreign corporation must include on its U.S. income tax return in order to claim an exemption.

In general, a foreign corporation must own or lease an entire ship or aircraft, and the ship or aircraft must carry cargo or passengers for hire, in order for the foreign corporation to be engaged in the operation of a ship or aircraft for this purpose. Section 1.883–1(e). Section 1.883–1(f) provides rules for determining whether income is derived from the international operation of a ship or aircraft. Section 1.883–1(g)(1) provides rules for determining whether certain activities of a foreign corporation that is engaged in the international operation of ships or aircraft are so closely related to that operation as to be considered incidental to the international operation of ships or aircraft. The final regulations provide a nonexclusive list of activities that are considered incidental to the international operation of ships or aircraft. Income from these incidental activities is deemed to be income derived from the international operation of a ship or aircraft for purposes of the exclusion under section 883. Section 1.883–1(g)(2) also provides a nonexclusive list of activities that are not incidental to the international operation of ships or aircraft. The final regulations reserve on whether services, including ground services, maintenance, catering, and other services, are considered incidental to the international operation of ships or aircraft.

Section 1.883–1(h) provides that an equivalent exemption may exist if a foreign country generally imposes no tax on income or specifically provides a domestic tax law exemption for income derived from the international operation of ships or aircraft. Alternatively, a foreign country may exchange a diplomatic note, or enter into an agreement, with the United States that provides for a reciprocal exemption for purposes of section 883. Section 1.883–1(h)(3)(i) generally provides that a foreign country that grants an exemption from taxation for income from the international operation of ships or aircraft solely through an income tax convention with the United States is not considered to grant an equivalent exemption. Thus, a corporation organized in such a country may not claim an exclusion under section 883, and can only claim available treaty benefits to exempt income derived from international transport.

The final regulations require that a foreign corporation must satisfy one of three stock ownership tests to satisfy the ownership requirements of section 883(c): A publicly-traded test in § 1.883–2(a), a CFC stock ownership test in § 1.883–3(a), or a qualified shareholder stock ownership test in § 1.883–4(a). Under § 1.883–3(a), a foreign corporation satisfies the CFC stock ownership test if it meets an ''income inclusion test'' and satisfies certain substantiation and reporting requirements under § 1.883–3(c) and (d). The income inclusion test requires that more than 50 percent of the CFC's adjusted net foreign base company income (as defined in § 1.954–1(d) and as increased or decreased by section 952(c)) derived from the international operation of ships or aircraft be includible in the gross income of one or more U.S. citizens, individual residents of the United States, or domestic corporations. Section 1.883–3(b). This rule prevents individuals residing in foreign countries that do not grant an equivalent exemption to U.S. corporations from benefiting from the section 883 exemption by owning a CFC through a domestic partnership, estate or trust.

Section 1.883–4 of the final regulations provides rules for when a foreign corporation satisfies the qualified shareholder stock ownership test. To satisfy this test, qualified shareholders must own (applying the attribution rules of § 1.883–4(c)) more than 50 percent of the value of a foreign corporation's outstanding shares for half the number of days in the corporation's taxable year. The foreign corporation must also meet the substantiation and reporting requirements of § 1.883–4(d) and (e). Under the reporting requirements of § 1.883–4(e), a foreign corporation must attach a statement with certain information to its Form 1120–F, ''U.S. Income Tax Return of a Foreign Corporation,'' including the names and addresses of individual shareholders with large shareholdings (at least 5 percent) in the foreign corporation.

2. Elimination of Foreign Base Company Shipping Income

Section 415 of the American Jobs Creation Act of 2004 (Pub. L. 108–357 (118 Stat. 1418) (AJCA) repealed section 954(a)(4) and (f), eliminating foreign base company shipping income as a type of foreign base company income, and therefore, as subpart F income. The repeal is effective for taxable years of foreign corporations beginning after December 31, 2004, and for taxable years of United States shareholders with or within which such taxable years of foreign corporations end. Section 423 of AJCA also delayed the applicability date of the final regulations under section 883(a) and (c) for one year, until taxable years beginning after September 24, 2004.

Commentators noted that the repeal of the foreign base company shipping provisions created uncertainty about the application of the income inclusion test for CFCs that no longer have foreign base company income.

On August 5, 2005, the IRS and the Treasury Department issued TD 9218 (70 FR 45529) to conform the applicability date of the final regulations in light of section 423 of AJCA. The preamble to TD 9218 also acknowledged commentators' concerns regarding the application of the income inclusion test after the repeal of the foreign base company shipping provisions. The preamble stated that a CFC that satisfied the income inclusion test prior to the effective date of section 415 of AJCA would continue to satisfy that test after the effective date of the legislation, provided the CFC is able to demonstrate that if the foreign base company shipping provisions had not been repealed, more than 50 percent of the its current earnings and profits derived from the international operation of ships or aircraft would have been attributable to amounts includible in the gross income of one or more U.S. citizens, individual residents of the United States, or domestic corporations (pursuant to section 951(a)(1)(A) or another provision of the Code) for the

taxable years of such persons in which the taxable year of the CFC ends.

The preamble to TD 9218 also stated that the IRS and the Treasury Department would issue regulations to clarify the application of the income inclusion test, and invited further comments on the most appropriate way to accomplish a clarification consistent with the principles of the existing section 883 regulations, and the repeal of the foreign base company shipping provisions.

3. Issuance of Notice 2006–43

The IRS and the Treasury Department received a number of comments in response to the preamble language in TD 9218 dealing with the income inclusion test. Generally, commentators stated that to require CFCs to calculate hypothetical amounts of subpart F income as though the foreign base company shipping provisions had not been repealed was too complex an approach to administer properly. Commentators proposed several alternative approaches they viewed as simpler to the approach described in TD 9218.

After considering these comments, the IRS and the Treasury Department issued Notice 2006–43, ''Interim Guidance With Respect to the Application of Treas. Reg. § 1.883–3,'' (2006–21 IRB 921 (May 22, 2006)), which announced a new approach. Under the Notice, a CFC would satisfy the stock ownership test of § 1.883–1(c)(2) if it met a ''qualified U.S. person ownership test'' and satisfied revised substantiation and reporting requirements. To satisfy the qualified U.S. person ownership test, a corporation would be required to be a CFC for more than half the days of its taxable year, and more than 50 percent of the total value of the CFC's outstanding stock would have to be owned (within the meaning of section 958(a) as modified by the Notice) by one or more qualified U.S. persons for more than half the days of its taxable year. See § 601.601(d)(2).

These temporary regulations incorporate the rules of Notice 2006–43, with certain amendments, and respond to comments that have been received concerning other portions of the existing section 883 regulations.

4. Additional Comments

The following additional comments were received regarding the final regulations.

A. Ground Services

The final regulations reserved on whether the performance of a variety of ground services should be treated as activities that are incidental to the international operation of ships or aircraft. Section 1.883–1(g)(3). The IRS and the Treasury Department have received a number of comments from the air transport industry requesting guidance under section 883 on the treatment of ground services, including cargo handling, maintenance services, catering, and customer service. Commentators have pointed to recent changes in the Commentaries to Article 8 (Shipping, Inland Waterways Transport and Air Transport) of the Model Tax Convention on Income and on Capital published by the Organisation for Economic Co-operation and Development (the OECD Model Convention) that clarify the circumstances under which certain services performed by an enterprise engaged in the operation of ships or aircraft in international traffic may be either ancillary or directly related to such operations, and thereby covered services for purposes of Article 8 of the OECD Model Convention.

B. U.S. Income Tax Conventions as Equivalent Exemptions

Commentators have also suggested that countries that provide an exemption to U.S. corporations only through an income tax convention with the United States should be treated as granting an equivalent exemption for purposes of section 883. In support of their position, commentators cite the Senate Committee Report to the Tax Reform Act of 1986 (Pub. L. 99–514 (100 Stat. 2085)), which states:

> The committee intends that a country which, as a result of a treaty with the United States, exempts U.S. citizens and domestic corporations from tax in the country on income derived from the operation of ships or aircraft, has an equivalent exemption, even though the treaty technically contains certain additional requirements other than residence, such as U.S. registration or documentation of the ship or aircraft.

(S. Rep. No. 99–313, at 343–44 (1986))

Prior to 2001, a foreign country that provided an exemption from taxation for income from the international operation of ships or aircraft through an income tax convention was treated as granting an equivalent exemption for purposes of section 883. See Rev. Rul. 89–42 (1989–1 CB 234); Rev. Rul. 97–31 (1997–2 CB 77) (supplementing Rev. Rul. 89–42). In 2001, however, the IRS and the Treasury Department reconsidered this position, and concluded that an exemption under an income tax convention could not constitute an equivalent exemption for purposes of section 883(a) because the Code and income tax conventions have different eligibility requirements, and provide exemptions that vary in scope. See Rev. Rul. 2001–48 (2001–2 CB 324) (modifying and superseding Rev. Rul. 97–31). The position taken in Rev. Rul. 2001–48 was incorporated into § 1.883–1(h)(3)(i) of the final regulations. See § 601.601(d)(2).

C. Reporting Requirements Related to Qualified Shareholder Stock Ownership Test

In connection with the substantiation and reporting requirements for the qualified shareholder stock ownership test under § 1.883–4(a), the IRS and the Treasury Department have continued to receive comments expressing concern over the requirement that the names and addresses of individual shareholders with large shareholdings (at least 5 percent) in corporations relying on this ownership test be disclosed on Form 1120–F. Recent comments have suggested that in lieu of providing such names and addresses, taxpayers should be permitted to submit a sworn statement by a U.S. tax practitioner subject to Circular 230 with their return that states that the taxpayer satisfies the qualified shareholder stock ownership test, and that the names and addresses of shareholders with large shareholdings are available for inspection by the IRS at the office of that such practitioner.

Explanation of Provisions

These temporary regulations incorporate the rules of Notice 2006–43 and also address a number of comments that have been received concerning other portions of the existing section 883 regulations.

1. Modifications to the Income Inclusion Test

These temporary regulations generally adopt the qualified U.S. person ownership test contained in Notice 2006–43. A CFC meets the qualified U.S. person ownership test in § 1.883–3T(b)(1) only if more than 50 percent of the total value of all the outstanding stock of the CFC is owned (within the meaning of section 958(a), as modified in § 1.883–3T(b)(4)), by one or more qualified U.S. persons. The term *qualified U.S. person* means a U.S. citizen, resident alien, domestic corporation, or domestic trust described in section 501(a). For purposes of applying the qualified U.S. person ownership test, the value of the stock of the CFC that is owned (directly or indirectly) through bearer shares is not taken into account in the numerator, but is taken into account in the denominator to determine the portion of the overall

stock value that is owned by qualified U.S. persons. Section 1.883–3T(b)(3).

For purposes of applying the qualified U.S. person ownership test, the attribution rules of section 958(a) will apply to determine the ownership interests of qualified U.S. persons held through foreign entities. In addition, the temporary regulations extend the attribution rules of section 958(a) to domestic partnerships, domestic trusts not described in section 501(a), and domestic estates. In the case of these domestic entities, stock will be treated as owned proportionately by the partners, beneficiaries, grantors, or other interest holders in such entities, respectively, applying the rules of section 958(a) as if the domestic partnership, estate, or trust were a foreign partnership, estate, or trust, respectively. The regulations also contain conforming changes to the substantiation and reporting provisions in this section to reflect the new qualified U.S. person ownership test for CFCs. A CFC that fails this test will not be a qualified foreign corporation unless it meets either the publicly-traded test of § 1.883–2(a) or the qualified shareholder stock ownership test of § 1.883–4(a).

2. Activities Incidental to the International Operation of Ships or Aircraft

The IRS and the Treasury Department recognize that guidance is needed on the extent to which ground services that are conducted by foreign corporations engaged in the international operation of ships or aircraft are so closely related to such operation that they are considered activities incidental to the international operation of ships or aircraft. Section 1.883–1T(g)(1)(xi) treats the provision of goods and services by engineers, ground and equipment maintenance staff, cargo handlers, catering staff, and customer services personnel, and the provision of facilities such as passenger lounges, counter space, ground handling equipment, and hanger facilities as activities incidental to the international operation of a ship or aircraft. The regulations also make clear that such services will be treated as incidental, whether provided to another enterprise as part of a pooling arrangement, alliance, or other joint venture.

3. Countries Providing an Exemption Only Through an Income Tax Convention

In response to comments and further study, the IRS and the Treasury Department believe that it is appropriate to provide additional guidance on when a country that only provides for an exemption by means of an income tax convention with the United States will be considered as granting an equivalent exemption for purposes of section 883(a). Section 1.883–1(h)(1), which sets forth the various bases on which equivalent exemptions may be claimed, is broadened by § 1.883–1T(h)(1)(ii) to include a domestic tax law exemption by income tax convention. Section 1.883–1T(h)(3) sets out the conditions under which an exemption under an income tax convention may constitute an equivalent exemption.

If a foreign country provides an exemption from tax under a shipping and air transport or gains article of an income tax convention with the United States, and it does not otherwise provide an equivalent exemption through a diplomatic note, domestic statutory law, or by generally not imposing income tax on foreign corporations engaged in the international operation of ships or aircraft, a corporation organized in that country may treat that income tax convention as providing an equivalent exemption for purposes of section 883, but only if the foreign corporation meets all the conditions for claiming benefits with respect to such income under the income tax convention, and the category of income for which the convention grants benefits is also described in § 1.883–1(h)(2).

For example, if a foreign corporation is seeking an exemption with respect to non-incidental container-related income, it may not treat an exemption provided by an income tax convention for that type of income as an equivalent exemption, because that category of income is not listed in § 1.883–1(h)(2). Equivalent exemptions are determined separately with respect to each category of income listed in § 1.883–1(h)(2). As a result, the foreign corporation may treat an exemption under an income tax convention with respect to another category of income that is listed in § 1.883–1(h)(2) (for example, incidental bareboat charter income) as an equivalent exemption for purposes of section 883.

A foreign corporation that is entitled to treat an income tax convention as providing an equivalent exemption with respect to a particular category of income under § 1.883–1T(h)(1)(ii) will not always qualify for an exclusion from gross income under section 883. For example, a corporation that is a resident of a foreign country for purposes of an income tax convention because that is where it is managed and controlled is not a qualified foreign corporation under § 1.883–1(c)(1), and may not claim an exclusion from gross income under section 883, if it is not also organized in that country. Similarly, a foreign corporation that does not meet one of the stock ownership tests described in § 1.883–1(c)(2) is not a qualified foreign corporation under § 1.883–1(c)(1), and may not claim an exclusion from gross income under section 883, even though it would satisfy the limitation on benefits article under the relevant convention.

4. Countries That Provide an Exemption Through an Income Tax Convention and by Other Means

As provided in the final regulations, a foreign corporation that qualifies for an exemption from tax under an income tax convention and an equivalent exemption under section 883 through a diplomatic note, domestic statutory law, or by generally imposing no income tax on foreign corporations engaged in the international operation of ships or aircraft will continue to have the choice of whether to claim an exemption under the income tax convention or under section 883. Section 1.883–1T(h)(3)(ii)(A). If a foreign corporation chooses to claim an exemption under an income tax convention, it may also choose to claim an exemption under section 883 for any category of income listed in § 1.883–1(h)(2), to the extent that such income is also exempt under an income tax convention. Section 1.883–1T(h)(3)(ii)(B).

The rules provided in § 1.883–1(h)(3)(iii) of the final regulations for certain joint ventures also continue in modified form. A foreign corporation resident in a country that only provides an exemption through an income tax convention with the United States, and that participates in a joint venture entity that is fiscally transparent for U.S. tax purposes but not under the law of the treaty jurisdiction, will not be able to take advantage of the new rules on equivalent exemptions under income tax conventions, and must rely on § 1.883–1T(h)(3)(iii).

5. Reporting Requirements Related to Qualified Shareholder Stock Ownership Test

Upon further study and review, the IRS and the Treasury Department have decided to bring the disclosure required under each of the stock ownership tests provided in § 1.883–1(c)(2) into greater accord with the disclosure required for comparable stock ownership tests with similar tax policy objectives. For example, reporting in conjunction with the stock ownership tests found in the branch profits tax regulations and limitation on benefits articles in U.S.

income tax conventions does not require the disclosure of certain shareholder names and addresses to the IRS. See § 1.884–5 and Form 8833, ''Treaty-Based Return Position Disclosure Under Section 6114 or 7701(b).'' Consequently, these regulations have eliminated the requirement that the names and addresses of shareholders in corporations relying on the various stock ownership tests in § 1.883–1(c)(1) (that is, under the closely held exception to the publicly-traded test, the CFC stock ownership test, and the qualified shareholder stock ownership test) be disclosed on Form 1120–F. See §§ 1.883–2T(e), 1.883–3T(c), and 1.883–4T(d).

Foreign corporations will continue to have to report on Form 1120–F certain summary information regarding the shareholdings that are relied upon to satisfy the applicable stock ownership test (for example, aggregate percentage of interests held by shareholders by country of residence). Under new § 1.883–1T(c)(3)(i)(G), they also will have to report whether any shareholder whose stock holdings are relied upon to meet an ownership test holds such stock either directly or indirectly through bearer shares. In addition, each qualified shareholder and intermediary (if any) must declare under penalties of perjury that its ownership interest in the foreign corporation or any corporate intermediary is not held through bearer shares. Conforming amendments to the substantiation and documentation requirements in §§ 1.883–2T(e) and 1.883–4T(d)(4) have been made.

Commentators suggested alternative methods for making the names and addresses of 5-percent shareholders available to the IRS. However, these methods were not adopted due to the complexity of the regimes proposed, and questions as to whether such approaches would in fact address the commentators' concerns. Instead, the IRS and the Treasury Department chose to rely on procedures already in place in § 1.883–1(c)(3) and as modified by § 1.883–1T(c)(3), which requires, among other things, that a foreign corporation obtain ownership statements to document and substantiate all representations it has made on Form 1120–F, and that it provide substantiating documentation in response to a written request from the Commissioner. Such information must be provided to the IRS within 30 days (rather than the 60 days allowed by § 1.883–1(c)(3)) of a written request by the Commissioner, because the names and addresses of relevant shareholders will no longer be provided on the Form 1120–F by taxpayers. See § 1.883–1T(c)(3).

The IRS and the Treasury Department believe that these revised reporting rules will simultaneously reduce disclosure concerns raised by taxpayers and encourage greater reporting of the information the IRS needs to administer section 883. The IRS and the Treasury Department also believe these changes, in conjunction with the remaining reporting requirements in §§ 1.883–2(f), 1.883–2T(f), 1.883–3T(d), 1.883–4(e), and 1.883–4T(e), will provide sufficient information to ensure the sound and efficient administration of section 883.

Effective Dates

See § 1.883–5T(d) for effective date of these temporary regulations and § 1.883–5T(e) for applicability dates that apply to these temporary regulations.

Effect on Other Documents

The following publications are modified as of June 25, 2007:

Notice 2006–43 (2006–21 IRB 921 (May 22, 2006))

Rev. Rul. 2001–48 (2001–2 CB 324)

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), please refer to the Special Analyses section of the preamble to the cross-reference notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Patricia A. Bray of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

■ Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 2.** Section 1.883–0 is amended by:

■ 1. Revising the entries for § 1.883–1(g)(3) and (h)(3).

■ 2. Revising the entry for § 1.883–2(e)(2).

■ 3. Revising the entry for § 1.883–3.

■ 4. Adding the entries for § 1.883–5(d) and (e).

The revisions and additions read as follows:

§ 1.883–0 Outline of major topics.

* * * * *

§ 1.883–1 Exclusion of income from the international operation of ships or aircraft.

* * * * *

(g) * * *

(3) [Reserved]. For further guidance, see the entry for § 1.883–1T(g)(3).

* * * * *

(h) * * *

(3) [Reserved]. For further guidance, see the entries for § 1.883–1T(h)(3).

* * * * *

§ 1.883–2 Treatment of publicly-traded corporations.

* * * * *

(e)(2) [Reserved]. For further guidance, see the entry for § 1.883–2T(e)(2).

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§ 1.883–3 Treatment of controlled foreign corporations.

[Reserved]. For further guidance, see the entry for § 1.883–3T.

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§ 1.883–5 Effective/applicability dates.

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(d) [Reserved]. For further guidance, see the entry for § 1.883–5T(d).

(e) [Reserved]. For further guidance, see the entry for § 1.883–5T(e).

■ **Par. 3.** Section 1.883–0T is added to read as follows:

§ 1.883–0T Outline of major topics (temporary).

This section lists the major paragraphs contained in §§ 1.883–1T through 1.883–5T.

§ 1.883–1T Exclusion of income from the international operation of ships or aircraft (temporary).

(a) through (c)(3)(i) [Reserved]. For further guidance, see entries for § 1.883–1(a) through (c)(3)(i).

(ii) Further documentation.

(A) General rule.

(B) Names and addresses of certain shareholders.

(c)(4) through (g)(2) [Reserved]. For further guidance, see entries for § 1.883–1(c)(4) through (g)(2).

(3) Other services. [Reserved].

(g)(4) through (h)(2) [Reserved]. For further guidance, see entries for § 1.883–1(g)(4) through (h)(2).

(3) Special rules with respect to income tax conventions.

(i) Countries with only an income tax convention.

(ii) Countries with both an income tax convention and an equivalent exemption.

(A) General rule.

(B) Special rule for simultaneous benefits under section 883 and an income tax convention.

(iii) Participation in certain joint ventures.

(iv) Independent interpretation of income tax conventions.

(h)(4) through (j) [Reserved]. For further guidance, see entries for § 1.883–1(h)(4) through (j).

§ 1.883–2T Treatment of publicly-traded corporations (temporary).

(a) through (e)(1) [Reserved]. For further guidance, see entries for § 1.883–2(a) through (e)(1).

(2) Availability and retention of documents for inspection.

(f) [Reserved]. For further guidance, see entry for § 1.883–2(f).

§ 1.883–3T Treatment of controlled foreign corporations (temporary).

(a) General rule.

(b) Qualified U.S. person ownership test.

(1) General rule.

(2) Qualified U.S. person.

(3) Treatment of bearer shares.

(4) Attribution of ownership through certain domestic entities.

(5) Examples.

(c) Substantiation of CFC stock ownership.

(1) In general.

(2) Ownership statements from qualified U.S. persons.

(3) Ownership statements from intermediaries.

(4) Three-year period of validity.

(5) Availability and retention of documents for inspection.

(d) Reporting requirements.

§ 1.883–5T Effective/applicability dates (temporary).

(a) through (c) [Reserved]. For further guidance, see entries for § 1.883–5(a) through (c).

(d) Effective date.

(e) Applicability dates.

(f) Expiration date.

■ **Par. 4.** Section 1.883–1 is amended by:

■ 1. Revising paragraphs (c)(3)(i)(D), (c)(3)(ii), (g)(1)(ix), (g)(1)(x), (g)(3), (h)(1)(ii), and (h)(3).

■ 2. Revising paragraphs (c)(3)(i)(G) and (H).

■ 3. Adding new paragraph (c)(3)(i)(I).

■ 4. Adding paragraph (g)(1)(xi).

■ 5. Revising paragraph (g)(3).

The revisions and additions read as follows:

§ 1.883–1 Exclusion of income from the international operation of ships or aircraft.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(D) [Reserved]. For further guidance, see § 1.883–1T(c)(3)(i)(D).

* * * * *

(G) through (I) [Reserved]. For further guidance, see § 1.883–1T(c)(3)(i)(G) through (I).

(ii) [Reserved]. For further guidance, see § 1.883–1T(c)(3)(ii).

* * * * *

(g) * * *

(1) * * *

(ix) through (xi) [Reserved]. For further guidance, see § 1.883–1T(g)(1)(ix) through (xi).

(2) * * *

(3) [Reserved]. For further guidance, see § 1.883–1T(g)(3).

* * * * *

(h) * * *

(1) * * *

(ii) [Reserved]. For further guidance, see § 1.883–1T(h)(1)(ii).

* * * * *

(3) [Reserved]. For further guidance, see § 1.883–1T(h)(3).

* * * * *

■ **Par. 5.** Section 1.883–1T is added to read as follows:

§ 1.883–1T Exclusion of income from the international operation of ships or aircraft (temporary).

(a) through (c)(3)(i)(C) [Reserved]. For further guidance, see § 1.883–1(a) through (c)(3)(i)(C).

(D) The applicable authority for an equivalent exemption, for example, the citation of a statute in the country where the corporation is organized, a diplomatic note between the United States and such country, or an income tax convention between the United States and such country in the case of a corporation described in paragraphs (h)(3)(i) through (iii) of this section;

(c)(3)(i)(E) through (F) [Reserved]. For further guidance, see § 1.883–1(c)(3)(i)(E) through (F).

(G) A statement that none of the foreign corporation's shares or shares of any intermediary entity, if any, that are held by qualified shareholders and relied on to satisfy any of the stock ownership tests described in § 1.883–1(c)(2) are issued in bearer form;

(H) Any other information required under § 1.883–2(f), § 1.883–2T(f), § 1.883–3T(d), § 1.883–4(e), or § 1.883–4T(e), as applicable; and

(I) Any other relevant information specified in Form 1120-F, ''U.S. Income Tax Return of a Foreign Corporation,'' and its accompanying instructions.

(ii) *Further documentation*—(A) *General rule.* Except as provided in this paragraph (c)(3)(ii)(B), if the Commissioner requests in writing that the foreign corporation document or substantiate representations made under paragraph (c)(3)(i) of this section, or under § 1.883–2(f), § 1.883–2T(f), § 1.883–3T(d), § 1.883–4(e), or § 1.883–4T(e), as applicable, the foreign corporation must provide the documentation or substantiation within 60 days following the written request. If the foreign corporation does not provide the documentation and substantiation requested within the 60-day period, but demonstrates that the failure was due to reasonable cause and not willful neglect, the Commissioner may grant the foreign corporation a 30-day extension. Whether a failure to obtain the documentation or substantiation in a timely manner was due to reasonable cause and not willful neglect shall be determined by the Commissioner after considering all the facts and circumstances.

(B) *Names and addresses of certain shareholders.* If the Commissioner requests the names and permanent addresses of individual qualified shareholders of a foreign corporation, as represented on each such individual's ownership statement, to substantiate the requirements of the exception to the closely-held test in the publicly-traded test in § 1.883–2(e), the qualified shareholder stock ownership test in § 1.883–4(a), or the qualified U.S. person ownership test in § 1.883–3T(b), the foreign corporation must provide the documentation and substantiation within 30 days following the written request. If the foreign corporation does not provide the documentation and substantiation within the 30-day period, but demonstrates that the failure was due to reasonable cause and not willful neglect, the Commissioner may grant the foreign corporation a 30-day extension. Whether a failure to obtain the documentation or substantiation in a timely manner was due to reasonable cause and not willful neglect shall be determined by the Commissioner after considering all the facts and circumstances.

(c)(4) through (g)(1)(viii) [Reserved]. For further guidance see § 1.883–1(c)(4) through (g)(1)(viii).

(ix) Arranging by means of a space or slot charter for the carriage of cargo listed on a bill of lading or airway bill or similar document issued by the foreign corporation on the ship or aircraft of another corporation engaged in the international operation of ships or aircraft;

(x) The provision of containers and related equipment by the foreign corporation in connection with the international carriage of cargo for use by its customers, including short-term use within the United States immediately preceding or following the international carriage of cargo (and for this purpose, a period of five days or less shall be presumed to be short-term); and

(xi) The provision of goods and services by engineers, ground and equipment maintenance staff, cargo handlers, catering staff, and customer services personnel, and the provision of facilities such as passenger lounges, counter space, ground handling equipment, and hanger facilities.

(2) [Reserved]. For further guidance, see § 1.883–1(g)(2).

(3) *Other services.* [Reserved].

(g)(4) through (h)(1)(i) [Reserved]. For further guidance, see § 1.883–1(g)(4) through (h)(1)(i).

(ii) Specifically provides a domestic law tax exemption for income derived from the international operation of ships or aircraft, either by statute, decree, income tax convention, or otherwise; or

(h)(1)(iii) and (h)(2) [Reserved]. For further guidance, see § 1.883–1(h)(1)(iii) and (h)(2).

(3) *Special rules with respect to income tax conventions*—(i) *Countries with only an income tax convention.* If a foreign country only provides an exemption from tax for profits from the operation of ships or aircraft in international transport or international traffic under the shipping and air transport or gains article of an income tax convention with the United States, a foreign corporation organized in that country may treat that exemption as an equivalent exemption for purposes of section 883, but only if—

(A) The foreign corporation meets all the conditions for claiming benefits with respect to such profits under the income tax convention; and

(B) The profits that are exempt pursuant to the income tax convention also fall within a category of income described in paragraphs (h)(2)(i) through (viii) of this section.

(ii) *Countries with both an income tax convention and an equivalent exemption*—(A) *General rule.* If a foreign country provides an exemption from tax for profits from the operation of ships or aircraft in international transport or international traffic under the shipping and air transport or gains article of an income tax convention, and that foreign country also provides an equivalent exemption under section 883 by some other means for one or more categories of income under paragraph (h)(2) of this section, the foreign corporation may choose annually whether to claim an exemption under section 883 or the income tax convention. Except as provided in this paragraph (h)(3)(ii)(B), any such choice will apply with respect to all categories of qualified income of the foreign corporation and cannot be made separately with respect to different categories of income. If a foreign corporation bases its claim for an exemption on section 883, it must satisfy all of the requirements of this section to qualify for an exemption from U.S. income tax. If the foreign corporation bases its claim for an exemption on an income tax convention, it must satisfy all of the requirements for claiming benefits under the income tax convention. See § 1.883–4(b)(3) for rules about satisfying the stock ownership test of § 1.883–1(c)(2) using shareholders resident in a foreign country that offers an exemption under an income tax convention.

(B) *Special rule for simultaneous benefits under section 883 and an income tax convention.* If a foreign corporation is organized in a foreign country that offers an exemption from tax under an income tax convention and also by some other means, such as by diplomatic note or domestic statutory law, with respect to the same category of income, and the foreign corporation chooses to claim an exemption under an income tax convention under paragraph (h)(3)(ii)(A) of this section, it may simultaneously claim an exemption under section 883 with respect to a category of income exempt from tax by such other means if it satisfies the requirements of paragraphs (h)(3)(i)(A) and (B) of this section for each category of income, satisfies one of the stock ownership tests of paragraph (c)(2) of this section, and complies with the substantiation and reporting requirements in paragraph (c)(3) of this section.

(iii) *Participation in certain joint ventures.* A foreign corporation resident in a foreign country that provides an exemption only through an income tax convention will not be precluded from treating that exemption as an equivalent exemption if it derives income through a participation, directly or indirectly, in a pool, partnership, strategic alliance, joint operating agreement, code-sharing arrangement, or other joint venture described in § 1.883–1(e)(2), and the foreign corporation would be ineligible to claim benefits under the convention for that category of income solely because the joint venture was not fiscally transparent, within the meaning of § 1.894–1(d)(3)(iii)(A), with respect to that category of income under the income tax laws of the foreign corporation's country of residence.

(iv) *Independent interpretation of income tax conventions.* Nothing in §§ 1.883–1 through 1.883–5, or in this section and §§ 1.883–2T through 1.883–5T, affects the rights or obligations under any income tax convention. The definitions provided in §§ 1.883–1 through 1.883–5, or in this section and §§ 1.883–2T through 1.883–5T, shall not give meaning to similar terms used in any income tax convention, or provide guidance regarding the scope of any exemption provided by such convention, unless the income tax convention entered into force after August 26, 2003, and it, or its legislative history, explicitly refers to section 883 and guidance promulgated under that section for its meaning.

■ **Par. 6.** Section 1.883–2 is amended by revising paragraphs (e)(2), (f)(3), and (f)(4)(ii) to read as follows:

§ 1.883–2 Treatment of publicly-traded corporations.

* * * * *

(e) * * *

(2) [Reserved]. For further guidance, see § 1.883–2T(e)(2).

(f) * * *

(3) [Reserved]. For further guidance, see § 1.883–2T(f)(3).

(4) * * *

(ii) [Reserved]. For further guidance, see § 1.883–2T(f)(4)(ii).

* * * * *

■ **Par. 7.** Section 1.883–2T is added to read as follows:

§ 1.883–2T Treatment of publicly-traded corporations (temporary).

(a) through (e)(1) [Reserved]. For further guidance, see § 1.883–2(a) through (e)(1).

(2) *Availability and retention of documents for inspection.* The documentation described in § 1.883–2(e)(1) must be retained by the corporation seeking qualified foreign corporation status until the expiration of the statute of limitations for the taxable year of the foreign corporation to which the documentation relates. Such documentation must be made available for inspection by the Commissioner at such time and such place as the

Commissioner may request in writing in accordance with § 1.883–1T(c)(3)(ii)(A) or (B), as applicable.

(f) through (f)(2) [Reserved]. For further guidance, see § 1.883–2(f) through (f)(2).

(3) A description of each class of stock relied upon to meet the requirements of § 1.883–2(d), including whether the class of stock is issued in registered or bearer form, the number of issued and outstanding shares in that class of stock as of the close of the taxable year, and the value of each class of stock in relation to the total value of all the corporation's shares outstanding as of the close of the taxable year;

(4) and (4)(i) [Reserved]. For further guidance, see § 1.883–2(f)(4) and (f)(4)(i).

(ii) With respect to all qualified shareholders who own directly, or by application of the attribution rules in § 1.883–4(c), stock in the closely-held block of stock upon which the corporation intends to rely to satisfy the exception to the closely-held test of § 1.883–2(d)(3)(ii)—

(A) The total number of qualified shareholders, as defined in § 1.883–4(b)(1);

(B) The total percentage of the value of the shares owned, directly or indirectly, by such qualified shareholders by country of residence, determined under § 1.883–4(b)(2) (residence of individual shareholders) or § 1.883–4(d)(3) (special rules for residence of certain shareholders); and

(C) The days during the taxable year of the corporation that such qualified shareholders owned, directly or indirectly, their shares in the closely held block of stock.

(5) [Reserved]. For further guidance, see § 1.883–2(f)(5).

■ **Par. 8.** Section 1.883–3 is revised to read as follows:

§ 1.883–3 Treatment of controlled foreign corporations.

[Reserved]. For further guidance, see § 1.883–3T.

■ **Par. 9.** Section 1.883–3T is added to read as follows:

§ 1.883–3T Treatment of controlled foreign corporations (temporary).

(a) *General rule.* A foreign corporation satisfies the stock ownership test of § 1.883–1(c)(2) if it is a controlled foreign corporation (as defined in section 957(a)), satisfies the qualified U.S. person ownership test in paragraph (b) of this section, and satisfies the substantiation and reporting requirements of paragraphs (c) and (d) of this section, respectively. A CFC that fails the qualified U.S. person ownership test of paragraph (b) of this section will not satisfy the stock ownership test of § 1.883–1(c)(2) unless it meets either the publicly-traded test of § 1.883–2(a) or the qualified shareholder stock ownership test of § 1.883–4(a).

(b) *Qualified U.S. person ownership test*—(1) *General rule.* A foreign corporation will satisfy the requirements of the qualified U.S. person ownership test only if it—

(i) Is a CFC for more than half the days in the corporation's taxable year; and

(ii) More than 50 percent of the total value of its outstanding stock is owned (within the meaning of section 958(a) and paragraph (b)(4) of this section) by one or more qualified U.S. persons for more than half the days of the CFC's taxable year, provided such days of ownership are concurrent with the time period during which the foreign corporation satisfies the requirement in paragraph (b)(1)(i) of this section.

(2) *Qualified U.S. person.* For purposes of this section, the term *qualified U.S. person* means a U.S. citizen, resident alien, domestic corporation, or domestic trust described in section 501(a), but only if the person provides the CFC with an ownership statement as described in paragraph (c)(2) of this section, and the CFC meets the reporting requirements of paragraph (d) of this section with respect to that person.

(3) Treatment of bearer shares. For purposes of applying the qualified U.S. person ownership test, the value of the stock of a CFC that is owned (directly or indirectly) through bearer shares by qualified U.S. persons is not taken into account in the numerator of the fraction, but is taken into account in the denominator to determine the portion of the value of stock owned by qualified U.S. persons.

(4) *Attribution of ownership through certain domestic entities.* For purposes of applying the qualified U.S. person ownership test of paragraph (b)(1) of this section, stock owned, directly or indirectly, by or for a domestic partnership, domestic trust not described in section 501(a), or domestic estate, shall be treated as owned proportionately by its partners, beneficiaries, grantors, or other interest holders, respectively, applying the rules of section 958(a) as if such domestic entity were a foreign entity. Stock considered to be owned by a person by reason of the preceding sentence shall, for purposes of applying such sentence, be treated as actually owned by such person.

(5) *Examples.* The qualified U.S. person ownership test of paragraph (b)(1) of this section is illustrated in the following examples:

Example 1. Ship Co is a CFC for more than half the days of Ship Co's taxable year. Ship Co is organized in a qualified foreign country. All of its shares are owned by a domestic partnership for the entire taxable year. All of the partners in the domestic partnership are citizens and residents of foreign countries. Ship Co fails the qualified U.S. person ownership test of paragraph (b)(1) of this section because none of the value of Ship Co's stock is owned, applying the attribution rules of paragraph (b)(4) of this section, for at least half the number of days of Ship Co's taxable year, by one or more qualified U.S. persons. Therefore, Ship Co must satisfy the qualified shareholder stock ownership test of § 1.883–4(a) in order to satisfy the stock ownership test of § 1.883–1(c)(2), and be considered a qualified foreign corporation.

Example 2. Ship Co is a CFC for more than half the days of its taxable year. Ship Co is organized in a qualified foreign country. Corp A, a foreign corporation whose stock is owned by a citizen and resident of a foreign country, owns 40 percent of the value of the stock of Ship Co for the entire taxable year. X, a domestic partnership, owns the remaining 60 percent of the value of the stock of Ship Co for Ship Co's entire taxable year. X is owned by 20 partners, all of whom are U.S. citizens and each of whom has owned a 5-percent interest in X for the entire taxable year of Ship Co. Ship Co satisfies the qualified U.S. person ownership test of paragraph (b)(1) of this section because 60 percent of the value of the stock of Ship Co is owned, applying the attribution of ownership rules of paragraph (b)(4) of this section, for at least half the number of days of Ship Co's taxable year by the partners of X, who are all qualified U.S. persons as defined in paragraph (b)(2) of this section. If Ship Co satisfies the substantiation and reporting requirements of paragraphs (c) and (d) of this section, it will meet the stock ownership test of § 1.883–1(c)(2).

Example 3. Ship Co is a foreign corporation organized in a qualified foreign country. Ship Co has two classes of stock, Class A representing 60 percent of the vote and value of all the shares outstanding of Ship Co, and Class B representing the remaining 40 percent of the vote and value of Ship Co. A, a U.S. citizen, holds for the entire taxable year all of the Class A stock, which is issued in bearer form, and B, a nonresident alien, owns all the Class B stock, which is in registered form. Ship Co cannot satisfy the qualified U.S. person ownership test of paragraph (b)(1) of this section because A's bearer shares cannot be taken into account as being owned by a qualified U.S. person in determining if the qualified U.S. person ownership test has been met; the shares are, however, taken into account in determining the total value of Ship Co's outstanding shares.

(c) *Substantiation of CFC stock ownership*—(1) *In general.* A foreign

corporation that relies on this CFC test to satisfy the stock ownership test of § 1.883–1(c)(2) must establish all the facts necessary to demonstrate to the Commissioner that it satisfies the qualified U.S. person ownership test of paragraph (b)(1) of this section. Specifically, the CFC must obtain a written ownership statement, signed under penalties of perjury by an individual authorized to sign that person's Federal tax or information return, from—

(i) Each qualified U.S. person upon whose stock ownership it relies to meet this test; and

(ii) Each domestic intermediary described in paragraph (b)(4) of this section, each foreign intermediary (including a foreign corporation, partnership, trust, or estate), and mere legal owners or record holders acting as nominees standing in the chain of ownership between each such qualified U.S. person and the CFC, if any.

(2) *Ownership statements from qualified U.S. persons.* A qualified U.S. person ownership statement must contain the following information:

(i) The qualified U.S. person's name, permanent address, and taxpayer identification number.

(ii) If the qualified U.S. person owns shares directly in the CFC, the number of shares of each class of stock of the CFC owned by the qualified person, the period of time during the taxable year of the CFC when the person owned the stock, and a representation that its interest in the CFC is not held through bearer shares.

(iii) If the qualified person owns an indirect interest in the CFC through an intermediary described in paragraph (c)(1)(ii) of this section, the name of that intermediary, the amount and nature of the interest in the intermediary, the period of time during the taxable year of the CFC when the person held such interest, and, in the case of an interest in a foreign corporate intermediary, a representation that such interest is not held through bearer shares.

(iv) Any other information as specified in guidance published by the Internal Revenue Service (see § 601.601(d)(2) of this chapter).

(3) *Ownership statements from intermediaries.* An intermediary ownership statement required of an intermediary described in paragraph (c)(1)(ii) of this section must contain the following information:

(i) The intermediary's name, permanent address, and taxpayer identification number, if any.

(ii) If the intermediary directly owns stock in the CFC, the number of shares of each class of stock of the CFC owned by the intermediary, the period of time during the taxable year of the CFC when the intermediary owned the stock, and a representation that such interest is not held through bearer shares.

(iii) If the intermediary indirectly owns the stock of the CFC, the name and address of each intermediary standing in the chain of ownership between it and the CFC, the period of time during the taxable year of the CFC when the intermediary owned the interest, the percentage of interest it holds indirectly in the CFC, and, in the case of a foreign corporate intermediary, a representation that its interest is not held through bearer shares.

(iv) Any other information as specified in guidance published by the Internal Revenue Service (see § 601.601(d)(2) of this chapter).

(4) *Three-year period of validity.* The rules of § 1.883–4(d)(2)(ii) apply for purposes of determining the validity of the ownership statements required under paragraph (c)(2) of this section.

(5) *Availability and retention of documents for inspection.* The documentation described in this paragraph (c) must be retained by the corporation seeking qualified foreign corporation status (the CFC) until the expiration of the statute of limitations for the taxable year of the CFC to which the documentation relates. Such documentation must be made available for inspection by the Commissioner at such place as the Commissioner may request in writing in accordance with § 1.883–1T(c)(3)(ii).

(d) *Reporting requirements.* A foreign corporation that relies on the CFC test of this section to satisfy the stock ownership test of § 1.883–1(c)(2) must provide the following information in addition to the information required by § 1.883–1(c)(3) to be included in its Form 1120–F, ''U.S. Income Tax Return of a Foreign Corporation,'' for the taxable year. The information must be based upon the documentation received by the foreign corporation pursuant to paragraph (c) of this section and must be current as of the end of the corporation's taxable year—

(1) The percentage of the value of the shares of the CFC that is owned by all qualified U.S. persons identified in paragraph (c)(2) of this section, applying the attribution of ownership rules of paragraph (b)(4) of this section;

(2) The period during which such qualified U.S. persons held such stock;

(3) The period during which the foreign corporation was a CFC;

(4) A statement that the CFC is directly held by qualified U.S. persons and does not have any bearer shares outstanding or, in the alternative, that it is not relying on direct or indirect ownership of such shares to meet the qualified U.S. person ownership test; and

(5) Any other relevant information specified by Form 1120–F, and its accompanying instructions, or in guidance published by the Internal Revenue Service (see § 601.601(d)(2) of this chapter).

■ **Par. 10.** Section 1.883–4 is amended by:

■ 1. Revising paragraphs (d)(4)(i)(C) and (d)(4)(i)(D).

■ 2. Removing paragraph (e)(2).

■ 3. Redesignating paragraphs (e)(3) and (e)(4) as paragraphs (e)(2) and (e)(3), respectively, and revising them.

The revisions read as follows:

§ 1.883–4 Qualified shareholder stock ownership test.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) and (D) [Reserved]. For further guidance, see § 1.883–4T(d)(4)(i)(C) and (D).

(e) * * *

(2) and (3) [Reserved]. For further guidance, see § 1.883–4T(e)(2) and (3).

■ **Par. 11.** Section 1.883–4T is added to read as follows:

§ 1.883–4T Qualified shareholder stock ownership test (temporary).

(a) through (d)(4)(i)(B) [Reserved]. For further guidance see § 1.883–4(a) through (d)(4)(i)(B).

(C) If the individual directly owns stock in the corporation seeking qualified foreign corporation status, the name of the corporation, the number of shares in each class of stock of the corporation that are so owned, with a statement that such shares are not issued in bearer form, and the period of time during the taxable year of the foreign corporation when the individual owned the stock;

(D) If the individual directly owns an interest in a corporation, partnership, trust, estate, or other intermediary that directly or indirectly owns stock in the corporation seeking qualified foreign corporation status, the name of the intermediary, the number and class of shares or the amount and nature of the interest of the individual in such intermediary, and, in the case of a corporate intermediary, a statement that such shares are not held in bearer form, and the period of time during the taxable year of the foreign corporation seeking qualified foreign corporation status when the individual held such interest;

(d)(4)(i)(E) through (e)(1) [Reserved]. For further guidance see § 1.883–4(d)(4)(i)(E) through (e)(1).

(2) With respect to all qualified shareholders relied upon to satisfy the 50 percent ownership test of § 1.883–4(a), the total number of such qualified shareholders as defined in § 1.883–4(b)(1); the total percentage of the value of the outstanding shares owned, applying the attribution rules of § 1.883–4(c), by such qualified shareholders by country of residence or organization, whichever is applicable; and the period during the taxable year of the foreign corporation that such stock was held by qualified shareholders; and

(3) Any other relevant information specified by the Form 1120–F, ''U.S. Income Tax Return of a Foreign Corporation,'' and its accompanying instructions, or in guidance published by the Internal Revenue Service (see § 601.601(d)(2) of this chapter).

■ **Par. 12.** Section 1.883–5 is amended by revising the heading and adding paragraphs (d) and (e) to read as follows:

§ 1.883–5 Effective/applicability dates.

* * * * *

(d) through (e) [Reserved]. For further guidance, see § 1.883–5T(d) through (e).

■ **Par. 13.** Section 1.883–5T is added to read as follows:

§ 1.883–5T Effective/applicability dates (temporary).

(a) through (c) [Reserved]. For further guidance, see § 1.883–5(a) through (c).

(d) *Effective date.* These regulations are effective on June 25, 2007.

(e) *Applicability dates.* Sections 1.883–1T, 1.883–2T, 1.883–3T, and 1.883–4T are applicable to taxable years of the foreign corporation beginning after June 25, 2007. Taxpayers may elect to apply § 1.883–3T to any open taxable years of the foreign corporation beginning on or after December 31, 2004.

(f) *Expiration date.* The applicability of §§ 1.883–1T, 1.883–2T, 1.883–3T, and 1.883–4T expires on or before June 22, 2010.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

■ **Par. 14.** The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

■ **Par. 15.** In § 602.101, paragraph (b) is amended by adding entries in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB Control No.
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§ 1.883–1T	1545–1667
§ 1.883–2T	1545–1667
§ 1.883–3T	1545–1667
§ 1.883–4T	1545–1667
§ 1.883–5T	1545–1667
* * * * *	

Kevin M. Brown,

Deputy Commissioner for Services and Enforcement.

Approved: June 14, 2007.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E7–12039 Filed 6–22–07; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 75

RIN 1219–AB52

Sealing of Abandoned Areas

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Extension of comment period.

SUMMARY: The Mine Safety and Health Administration (MSHA) is extending the comment period for the Emergency Temporary Standard (ETS) on sealing of abandoned areas of underground coal mines published on May 22, 2007 (72 FR 28796).

DATES: The comment period will close on August 17, 2007.

ADDRESSES: Comments must be clearly identified and may be submitted by any of the following methods:

(1) *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

(2) *Electronic mail: zzMSHA-Comments@dol.gov.* Include ''RIN 1219–AB52'' in the subject line of the message.

(3) *Telefax:* (202) 693–9441. Include ''RIN 1219–AB52'' in the subject.

(4) *Regular Mail:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939.

(5) *Hand Delivery or Courier:* MSHA, Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia 22209–3939. Sign in at the receptionist's desk on the 21st floor.

(6) *Docket:* Comments can be accessed electronically at *http://www.msha.gov* under the ''Rules and Regs'' link. MSHA will post all comments on the Internet without change, including any personal information provided. Comments may also be reviewed at the Office of Standards, Regulations, and Variances, 1100 Wilson Blvd., Room 2350, Arlington, Virginia. Sign in at the receptionist's desk on the 21st floor.

MSHA maintains a listserve that enables subscribers to receive e-mail notification when rulemaking documents are published in the **Federal Register**. To subscribe to the listserve, go to *http://www.msha.gov/subscriptions/subscribe.aspx.*

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939. Ms. Silvey can be reached at *Silvey.Patricia@dol.gov* (Internet E-mail), (202) 693–9440 (voice), or (202) 693–9441 (facsimile). This notice is available on the Internet at *http://www.msha.gov/REGSINFO.HTM.*

SUPPLEMENTARY INFORMATION: MSHA issued an ETS on May 22, 2007, which included hearing dates and a deadline for receiving comments. The comment period was scheduled to close on July 6, 2007, forty-five days from the date of publication, and the last hearing date was scheduled on July 19, 2007. MSHA believes this action allows commenters sufficient time to prepare comments including post-hearing comments. MSHA will accept written comments and other appropriate data for the record from any interested party up to the close of the comment period on August 17, 2007.

Dated: June 18, 2007.

Richard E. Stickler,

Assistant Secretary for Mine Safety and Health.

[FR Doc. E7–12242 Filed 6–22–07; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD01–07–072]

RIN 1625–AA00

Safety Zone; Boston Pops Fireworks, Boston, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the ''Boston Pops Esplanade Fireworks'' display on July 4, 2007 with a rain date of July 5, 2007 in Boston, Massachusetts, temporarily closing all navigable waters of the Charles River within a four hundred (400) yard radius of the fireworks launch barges located at approximate position 42°21.28′ N, 071°05.00′ W. The safety zone is necessary to protect the life and property of the maritime public from the potential hazards posed by a fireworks display. The safety zone temporarily prohibits entry into or movement within this portion of the Charles River during its closure period.

DATES: This rule is effective from 9 p.m. EDT on July 4, 2007 until 11:30 p.m. EDT on July 4, 2007 with a rain date of July 5, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD01–07–072 and are available for inspection or copying at Sector Boston, 427 Commercial Street, Boston, MA, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer Joseph Yonker, Sector Boston, Waterways Safety and Response Division, at (617) 223–5007.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The logistics with respect to the fireworks presentation were not determined with sufficient time to draft and publish an NPRM. Any delay encountered in this regulation's effective date would be contrary to the public interest since the safety zone is needed to prevent traffic from transiting a portion of the Charles River during the fireworks display and to provide for the safety of life on navigable waters.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay encountered in this regulation's effective date would be contrary to the public interest since the safety zone is needed to prevent traffic from transiting a portion of the Charles River during the fireworks event thus ensuring that the maritime public is protected from any potential harm associated with such an event.

Background and Purpose

''Boston 4 Celebrations,'' the organization responsible for Boston's Fourth of July event, is holding a fireworks display in honor of Independence Day. This rule establishes a temporary safety zone on the navigable waters of the Charles River within a four hundred (400) yard radius of the fireworks launch barges located at approximate position 42°21.28′ N, 071°05.00′ W. This safety zone is necessary to protect the maritime public from the dangers posed by this event. It will protect the public by prohibiting entry into or movement within the proscribed portion of the Charles River during the fireworks display.

Marine traffic may transit safely outside of the zone during the effective period. The Captain of the Port does not anticipate any negative impact on vessel traffic due to this event. Public notifications will be made prior to and during the effective period via safety marine information broadcasts and Local Notice to Mariners.

Discussion of Rule

This rule is effective from 9 p.m. EDT on July 4, 2007 until 11:30 p.m. EDT on July 4, 2007 with a rain date of 9 p.m. EDT on July 5, 2007 until 11:30 p.m. EDT on July 5, 2007. Marine traffic may transit safely outside of the safety zone in the majority of the Charles River during the event. Given the limited timeframe of the effective period of the zone, the size of the river and the size of the zone itself, the Captain of the Port anticipates minimal negative impact on vessel traffic due to this event. Public notifications will be made prior to and during the effective period via Local Notice to Mariners and marine information broadcasts.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule will prevent traffic from transiting a portion of the Charles River during this event, the effect of this rule will not be significant for several reasons: Vessels will be excluded from the area of the safety zone for only two and one-half hours, although vessels will not be able to transit the river in the vicinity of the zone, they will be able to operate in other areas of the river during the effective period; and advance notifications will be made to the local maritime community by marine information broadcasts and Local Notice to Mariners.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the Charles River from 9 p.m. until 11:30 p.m. EDT on July 4, 2007 or the same times on July 5, 2007 as a rain date. This safety zone will not have a significant economic impact on a substantial number of small entities for the reasons described under the Regulatory Evaluation section.

Assistance for Small Entities

Under subsection 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 [Pub. L. 104–121], the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. If this rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call Petty Officer Joseph Yonker, Sector Boston, Waterways Management Division, at (617) 223–5007.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture

Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g) of the Instruction, from further environmental documentation. This rule fits the category selected from paragraph (34)(g), as it would establish a safety zone that will be in effect for only two and one-half hours.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T07–072 to read as follows:

§ 165.T01–072 Safety Zone: Boston Pops Fireworks, Boston, Massachusetts.

(a) *Location.* The following area is a safety zone:

All navigable waters of the Charles River within a four hundred (400) yard radius of the fireworks launch barges located at approximate position 42°21.28′ N, 071°05.00′ W.

(b) *Effective Date.* This rule is effective from 9 p.m. EDT on July 4, 2007 until 11:30 p.m. EDT on July 4, 2007 with a rain date of 9 p.m. EDT on July 5, 2007 until 11:30 p.m. EDT July 5, 2007.

(c) *Definitions.* As applied to this section;

(1) Designated on-scene U.S. Coast Guard patrol personnel means commissioned officers, warrant officers, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, local, state, and federal law enforcement vessels.

(2) *[Reserved]*

(d) *Regulations.* (1) In accordance with the general regulations in 165.23 of this part, entry into or movement within this zone by any person or vessel is prohibited unless authorized by the Captain of the Port (COTP), Boston or the COTP's designated representative.

(2) All vessel operators shall comply with the instructions of the COTP or the designated on-scene U.S. Coast Guard patrol personnel. The safety zone is

closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative on VHF Channel 16 (156.8 MHz) to seek permission to do so. If permission is granted, vessel operators must comply with all directions given to them by the COTP or the COTP's designated representative.

Dated: June 12, 2007.

James L. McDonald,

Captain, U.S. Coast Guard, Captain of the Port, Boston, Massachusetts.

[FR Doc. E7–12137 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 07–027]

RIN 1625–AA00

Safety Zone; City of Richmond July 3rd Fireworks Show, San Francisco Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in the navigable waters of San Francisco Bay for the loading, transport, and launching of fireworks used during the City of Richmond Fireworks Display to be held on July 3, 2007. This safety zone is intended to prohibit vessels and people from entering into or remaining within the regulated areas in order to ensure the safety of participants and spectators.

DATES: This rule is effective from 8 a.m. to 10 p.m. on July 3, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of the docket COTP San Francisco Bay 07–027 are available for inspection or copying at Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Sheral Richardson United States Coast Guard Sector San Francisco, at (415) 556–2950 extension 136, or the 24-hour Command Center at (415) 399–3547.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Logistical details surrounding the event were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the event would occur before the rulemaking process was complete. Because of the dangers posed by the pyrotechnics used in this fireworks display, this safety zone is necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the pyrotechnics used in this fireworks display.

Background and Purpose

City of Richmond, Library and Community Department Recreation Division will sponsor a fireworks display on July 3, 2007, in the waters of San Francisco Bay on Richmond Inner Harbor near the Point Potrero. The fireworks display is meant for entertainment purposes. This safety zone is issued to establish a temporary restricted area in San Francisco Bay around the fireworks launch barge during loading of the pyrotechnics, during the transit of the barge to the display location, and during the fireworks display. This restricted area around the launch barge is necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barge. The Coast Guard has granted the event sponsor a marine event permit for the fireworks display.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone in the navigable waters of San Francisco Bay on Richmond Inner Harbor near Point Potrero. During the loading of the fireworks barge, while the barge is being towed to the display location, and until the start of the fireworks display, the temporary safety zone applies to the navigable waters around and under the fireworks barge within a radius of 100 feet. Fifteen minutes prior to and during the twenty minute fireworks display, the area to which the temporary safety zone applies will increase in size to encompass the navigable waters around and under the fireworks barge within a radius of 1,000 feet. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 3, 2007, and will take place at Pier 50 in San Francisco. Towing of the barge from Pier 50 to the display location is scheduled to take place between 6 p.m. and 8:30 p.m. on July 3, 2007. During the twenty minute fireworks display, scheduled to commence at approximately 9:15 p.m. on July 3, 2007, the fireworks barge will be located approximately 1,200 feet offshore from Point Potrero in the Richmond Inner Harbor in position 37°54.40′ N, 122°21.54′ W.

The effect of the temporary safety zone will be to restrict navigation in the vicinity of the fireworks barge while the fireworks are loaded at Pier 50, during the transit of the fireworks barge, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep spectators and vessels a safe distance away from the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this regulation prevents traffic from transiting a portion of San Francisco Bay during the event, the effect of this regulation will not be significant due to the small size and limited duration of the regulated area. The entities most likely to be affected are pleasure craft engaged in recreational activities and sightseeing. We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and

governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule is not expected to have a significant economic impact on a substantial number of entities, some of which may be small entities. This rule may affect owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (i) Vessel traffic can pass safely around the area, (ii) vessels engaged in recreational activities and sightseeing have ample space outside of the effected portion of San Francisco Bay to engage in these activities, (iii) this rule will encompass only a small portion of the waterway for a limited period of time, and (iv) the maritime public will be advised in advance of this safety zone via public notice to mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions, options for compliance, or assistance in understanding this rule, please contact Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 extension 136.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1 –888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165–T11–205 to read as follows:

§ 165–T11–205 Safety Zone; City of Richmond July 3rd Fireworks Show, San Francisco Bay, CA.

(a) *Location.* A safety zone is established for the waters of San Francisco Bay in the Richmond Inner Harbor surrounding a barge used as the launch platform for a fireworks display. During the loading of the fireworks barge, during the transit of the fireworks barge to the display location, and until fifteen minutes prior to the start of the fireworks display, the restricted area encompasses the navigable waters around and under the fireworks barge within a radius of 100 feet. During the fifteen minutes preceding the fireworks display and during the twenty minute fireworks display itself, the safety zone increases in size to encompass the navigable waters around and under the fireworks launch barge within a radius of 1,000 feet. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 3, 2007, and will take place at Pier 50 in San Francisco. Towing of the barge from Pier 50 to the display location is scheduled to take place between 6 p.m. and 8:30 p.m. on July 3, 2007. During the twenty minute fireworks display, scheduled to start at approximately 9:15 p.m. on July 3, 2007, the fireworks barge will be located approximately 1,000 feet offshore from Point Potrero in the Richmond Inner Harbor in position 37°54.40′ N, 122°21.54′ W.

(b) *Effective Period.* This section will be enforced from 8 a.m. to 10 p.m. on July 3, 2007. If the event concludes prior to the scheduled termination time, the Coast Guard will cease enforcement of the safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this safety zone by all vessels and persons is prohibited, unless specifically authorized by the Captain of the Port San Francisco, or his designated representative.

(d) *Enforcement.* All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, or the designated on-scene patrol personnel. Patrol personnel can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, Coast Guard Auxiliary, local, State, and Federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The U.S. Coast Guard may be assisted in the patrol and enforcement of this safety zone by local law enforcement as necessary.

Dated: June 13, 2007.

W.J. Uberti,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. E7–12140 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–07–034]

RIN 1625–AA00

Safety Zone; Mercyhurst College ''Old Fashion 4th of July'' Presque Isle Bay, Erie, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on Presque Isle Bay and Lake Erie near Erie, Pennsylvania. This zone is intended to restrict vessels from a portion of Presque Isle Bay and Lake Erie during the Mercyhurst College ''Old Fashion 4th of July'', fireworks display on July 4, 2007. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with fireworks displays.

DATES: This rule is effective from 10 p.m. (local) to 10:30 p.m. (local) on July 4, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket CGD09–07–034 and are available for inspection or copying at U.S. Coast Guard Sector Buffalo, 1 Fuhrmann Boulevard, Buffalo, NY 14203 between 8 a.m. (local) and 3 p.m. (local), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Tracy Wirth, U.S. Coast Guard Sector Buffalo, (716) 843–9573.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The permit application was not received in time to publish an NPRM followed by a final rule before the effective date. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property. The Coast Guard has not received any complaints or negative comments previously with regard to this event. For the same reasons, the Coast Guard also finds, under 5 U.S.C. 553(d)(3), that good cause exists for making this rule effective fewer than 30 days after publication in the **Federal Register**.

Background and Purpose

This temporary safety zone is necessary to protect vessels and spectators from the hazards associated with a fireworks display. Based on accidents that have occurred in other Captain of the Port zones, and the explosive hazards of fireworks, the Captain of the Port Buffalo has determined that fireworks launches proximate to watercraft pose a significant risk to public safety. The likely combination of large numbers of recreation vessels, congested waterways, darkness punctuated by bright flashes of light, and debris falling into the water could easily result in serious injuries or fatalities. Establishing a safety zone to control vessel movement around the location of the launch platform will help ensure the safety of persons and property at these events and help minimize the associated risks.

Discussion of Rule

A temporary safety zone is necessary to ensure the safety of spectators and vessels during the setup, loading and launching of a fireworks display in conjunction with the Mercyhurst College ''Old Fashion 4th of July'' fireworks display. The fireworks display will occur between 10 p.m. (local) and 10:30 p.m. (local) on July 4, 2007. The safety zone for the fireworks will encompass all waters of Presque Isle Bay and Lake Erie, Erie, PA within a five hundred foot radius of position 42°08′41″ N, 080°06′40″ W. [DATUM: NAD 83].

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene representative. The Captain of the Port or his designated on-scene

representative may be contacted on VHF Channel 16.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This determination is based on the minimal time that vessels will be restricted from the zone, and the zone is an area where the Coast Guard expects insignificant adverse impact to mariners from the zones' activation.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to transit or anchor in a portion of Presque Isle Bay and Lake Erie, near Erie, PA between 10 p.m. (local) and 10:30 p.m. (local) on July 4, 2007.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be in effect for only thirty minutes for one event. Vessel traffic can safely pass outside the safety zone during the event. In the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port Buffalo to transit through the safety zone. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined that these special local regulations and fishing rights protection need not be incompatible. We have also determined that this Rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Nevertheless, Indian Tribes that have questions concerning the provisions of this Proposed Rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are

technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedure; and related management system practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. That paragraph applies because this event establishes a safety zone. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T09–034 to read as follows:

§ 165.T09–034 Safety zone; Mercyhurst College ''Old Fashion 4th of July'', Presque Isle Bay, Erie, PA.

(a) *Location.* The following area is a temporary safety zone: All waters of Presque Isle Bay and Lake Erie, from surface to bottom, within a five hundred foot radius of position 42°08′41″ N, 080°06′40″ W. [DATUM: NAD 83].

(b) *Effective period.* This regulation is effective from 10 p.m. (local) to 10:30 p.m. (local), on July 4, 2007.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo, or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his designated on-scene representative may be contacted on VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo or his on-scene representative.

Dated: June 11, 2007.

S.J. Ferguson,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. E7–12141 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD01–07–031]

RIN 1625–AA00

Safety Zone; Town of Lynn Fourth of July Fireworks Display, Nahant Bay, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Town of Lynn Fourth of July Fireworks on July 3, 2007, temporarily closing all navigable waters of Nahant Bay within a 500 yard radius of the fireworks barge located at approximate position 42°27′41.2″ N, 70°55′6.1″ W. The safety zone is necessary to protect the life and property of the maritime public from the potential hazards posed by a fireworks display. The safety zone temporarily prohibits entry into or movement within this portion of Nahant Bay during the closure period.

DATES: This rule is effective from 8:15 p.m. EDT on July 3, 2007 until 9:45 p.m. EDT on July 3, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD01–07–031 and are available for inspection or copying at Sector Boston, 427 Commercial Street, Boston, MA between the hours of 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer Joseph Yonker, Sector Boston, Waterways Management Division, at (617) 223–5007.

SUPPLEMENTARY INFORMATION:

Regulatory History

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The fireworks display is scheduled to occur on July 3, 2007, and there is insufficient time to conduct a notice and comment rulemaking. Any delay in the regulation's effective date would be contrary to the public interest because the safety zone is needed to ensure the maritime public is protected from the potential harm associated with a fireworks display.

For the same reasons, the Coast Guard finds, under 5 U.S.C. 553(d)(3), that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

This rule establishes a safety zone on the navigable waters of Nahant Bay within a 500 yard radius around the fireworks barge located at approximate position 42°27′41.2″ N, 70°55′6.1″ W. The safety zone is in effect from 8:15 p.m. EDT until 9:45 p.m. EDT on July 3, 2007.

The safety zone temporarily restricts movement within this portion of Nahant Bay and is needed to protect the maritime public from the dangers posed by a fireworks display. Marine traffic may transit safely outside of the zone during the effective period. The Captain of the Port does not anticipate any negative impact on vessel traffic due to the event. Public notifications will be made prior to the effective period via marine information broadcasts and Local Notice to Mariners.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule prevents vessel traffic from transiting a portion of Nahant Bay during the effective period, the effects of this regulation will not be significant for several reasons: Vessels will be excluded from the proscribed area for one and one-half hours, vessels will be able to operate in the majority of Nahant Bay during the effective period, and advance notifications will be made to the local maritime community by marine information broadcasts and Local Notice to Mariners.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of Nahant Bay from 8:15 p.m. EDT until 9:45 p.m. EDT on July 3, 2007.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be in effect for only one and one-half hours, vessel traffic can safely pass around the zone, and advance notifications will be made to the local maritime community by marine information broadcasts and Local Notice to Mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not pose an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.1D

and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g) of the Instruction, from further environmental documentation. This paragraph applies because the rule would establish a safety zone.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T07–031 to read as follows:

§ 165.T07–031 Safety Zone; Town of Lynn Fourth of July Fireworks Display, Nahant Bay, Massachusetts.

(a) *Location.* The following area is a safety zone: All navigable waters of Nahant Bay, from surface to bottom, within a 500 yard radius of the fireworks barge located at approximate position 42°27′41.2″ N, 70°55′6.1″ W.

(b) *Effective Date.* This section is effective from 8:15 p.m. EDT until 9:45 p.m. EDT on July 3, 2007.

(c) *Definitions.* (1) As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port (COTP) in the enforcement of the safety zone.

(2) *[Reserved]*

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into or movement within this zone by any person or vessel is prohibited unless authorized by the COTP Boston or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative on VHF Channel 16 (156.8 MHz) to seek permission to do so in advance. If permission is granted, vessel operators must comply with all directions given to them by the COTP or the COTP's designated representative.

Dated: May 25, 2007.

James L. McDonald,

Captain, U. S. Coast Guard, Captain of the Port, Boston, Massachusetts.

[FR Doc. E7–12150 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–07–043]

RIN 1625–AA00

Safety Zone; Independence Day Fireworks Display, St. Lawrence River, Alexandria Bay, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the St. Lawrence River near Alexandria Bay, NY. This zone is intended to restrict vessels from a portion of the St. Lawrence River during the Independence Day Fireworks Display on July 4, 2007. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with fireworks displays.

DATES: This rule is effective from 9 p.m. (local) to 10 p.m. (local) on July 4, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket CGD09–07–043 and are available for inspection or copying at U.S. Coast Guard Sector Buffalo, 1 Fuhrmann Boulevard, Buffalo, NY 14203 between 8 a.m. (local) and 3 p.m. (local), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Tracy Wirth, U.S. Coast Guard Sector Buffalo; (716) 843–9573.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The permit application was not received in time to publish an NPRM followed by a final rule before the effective date. Delaying this rule would be contrary to the public interest of ensuring the safety of spectators and vessels during this event and immediate action is necessary to prevent possible loss of life or property. The Coast Guard has not received any complaints or negative comments previously with regard to this event. For the same reasons, the Coast Guard also finds, under 5 U.S.C. 553(d)(3), that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

This temporary safety zone is necessary to ensure the safety of vessels and spectators from hazards associated with a fireworks display. Based on accidents that have occurred in other Captain of the Port Zones, and the explosive hazards of fireworks, the Captain of the Port Buffalo has determined that fireworks launches proximate to watercraft pose a significant risk to public safety and property. The likely combination of large numbers of recreation vessels, congested waterways, darkness punctuated by bright flashes of light, and debris falling into the water could easily result in serious injuries or fatalities. Establishing a safety zone to control vessel movement around the location of the launch platform will help ensure the safety of persons and property at this event and help minimize the associated risks.

Discussion of Rule

A temporary safety zone is necessary to ensure the safety of spectators and vessels during the setup, loading and launching of a fireworks display in conjunction with the Independence Day Fireworks Display. The fireworks display will occur between 9 p.m. (local) and 10 p.m. (local) on July 4, 2007.

The safety zone for the fireworks will encompass all waters of the St. Lawrence River at Heart Island, Alexandria Bay, NY within a seven hundred foot radius of position 44°20′42″ N, 075°55′16″ W. [DATUM: NAD 83].

All persons and vessels must comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene representative. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Buffalo or his designated on-scene

representative. The Captain of the Port or his designated on-scene representative may be contacted on VHF Channel 16.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This determination is based on the minimal time that vessels will be restricted from the zone, and the zone is an area where the Coast Guard expects insignificant adverse impact to mariners from the zones' activation.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners and operators of vessels intending to transit or anchor in a portion of the St. Lawrence River near Alexandria Bay, NY between 9 p.m. (local) and 10 p.m. (local) on July 4, 2007.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will be in effect for only one hour for one event. Vessel traffic can safely pass outside the safety zone during the event. In the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port Buffalo to transit through the safety zone. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

The Coast Guard recognizes the treaty rights of Native American Tribes. Moreover, the Coast Guard is committed to working with Tribal Governments to implement local policies and to mitigate tribal concerns. We have determined that these special local regulations and fishing rights protection need not be incompatible. We have also determined that this Rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Nevertheless, Indian Tribes that have questions concerning the provisions of this Rule or options for compliance are encouraged to contact the point of contact listed under **FOR FURTHER INFORMATION CONTACT**.

Energy Effects

We have analyzed this rule under Executive order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are

technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedure; and related management system practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. That paragraph applies because this rule establishes a safety zone.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T09–043 to read as follows:

§ 165.T09–043 Safety zone; Independence Day Fireworks, St. Lawrence River, Alexandria Bay, NY.

(a) *Location.* The following area is a safety zone: All waters of the St. Lawrence River, at Heart Island, Alexandria Bay, NY, from surface to bottom, within a seven hundred foot radius of position 44°20′42″ N, 075°55′16″ W. [DATUM: NAD 83].

(b) *Effective period.* This regulation is effective from 9 p.m. (local) to 10 p.m. (local) on July 4, 2007.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Buffalo, or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Buffalo or his designated on-scene representative.

(3) The ''on-scene representative'' of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his designated on-scene representative may be contacted on VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone must contact the Captain of the Port Buffalo or his on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Buffalo or his on-scene representative.

Dated: June 11, 2007.

S.J. Ferguson,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. E7–12144 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 07–024]

RIN 1625–AA00

Safety Zone; Peninsula Celebration Association Annual Fireworks Spectacular, San Francisco Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone in the navigable waters of San Francisco Bay for the loading, transport, and launching of fireworks used during the Peninsula Celebration Association Annual Fireworks Spectacular Display to be held on July 4, 2007. This safety zone is intended to prohibit vessels and people from entering into or remaining within the regulated areas in order to ensure the safety of participants and spectators.

DATES: This rule is effective from 9 a.m. to 10 p.m. on July 4, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of the docket COTP San Francisco Bay 07–024 are available for inspection or copying at Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California, 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Sheral Richardson, United States Coast Guard Sector San Francisco, at (415) 556–2950 extension 136, or the 24-hour Command Center at (415) 399–3547.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Logistical details surrounding the event were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the event would occur before the rulemaking process was complete. Because of the dangers posed by the pyrotechnics used in this fireworks display, this Safety zone is necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the pyrotechnics used in this fireworks display.

Background and Purpose

Peninsula Celebration Association will sponsor a fireworks display on July 4, 2007 in the waters of San Francisco Bay on Redwood Creek near the Port of Redwood City. The fireworks display is meant for entertainment purposes. This safety zone is issued to establish a temporary restricted area in San Francisco Bay around the fireworks launch barge during loading of the pyrotechnics, during the transit of the barge to the display location, and during the fireworks display. This restricted area around the launch barge is

necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barge. The Coast Guard has granted the event sponsor a marine event permit for the fireworks display.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone in the navigable waters of San Francisco Bay near Pier 50 and in Redwood Creek. During the loading of the fireworks barge, while the barge is being towed to the display location, and until the start of the fireworks display, the temporary safety zone applies to the navigable waters around and under the fireworks barge within a radius of 100 feet. Fifteen minutes prior to and during the fifteen minute fireworks display, the area to which the temporary safety zone applies will increase in size to encompass the navigable waters around and under the fireworks barge within a radius of 1,000 feet. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 9 a.m. on July 4, 2007, and will take place at Pier 50 in San Francisco. Towing of the barge from Pier 50 to the display location is scheduled to take place between 12 p.m. and 8 p.m. on July 4, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m., the fireworks barge will be located approximately 600 feet off Wharf #5 in the Port of Redwood City in approximate position 37°30.35′ N, 122°12.85′ W.

The effect of the temporary safety zone will be to restrict navigation in the vicinity of the fireworks barge while the fireworks are loaded at Pier 50, during the transit of the fireworks barge, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the restricted area. These regulations are needed to keep spectators and vessels a safe distance away from the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

The Code of Federal Regulations prohibits any unauthorized person or vessel from entering or remaining in a safety zone. Vessels or persons violating this section will be subject to both criminal and civil penalties.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this regulation prevents traffic from transiting a portion of San Francisco Bay during the event, the effect of this regulation will not be significant due to the small size and limited duration of the regulated area. The entities most likely to be affected are pleasure craft engaged in recreational activities and sightseeing. We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule is not expected to have a significant economic impact on a substantial number of entities, some of which may be small entities. This rule may affect owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (i) Vessel traffic can pass safely around the area, (ii) vessels engaged in recreational activities and sightseeing have ample space outside of the effected portion of San Francisco Bay to engage in these activities, (iii) this rule will encompass only a small portion of the waterway for a limited period of time, and (iv) the maritime public will be advised in advance of this safety zone via public notice to mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions, options for compliance, or assistance in understanding this rule, please contact Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 extension 136.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not

an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165–T11–199 to read as follows:

§ 165–T11–199 Safety Zone; Peninsula Celebration Association Annual Fireworks Spectacular, San Francisco Bay, CA.

(a) *Location.* A safety zone is established for the waters of San Francisco Bay surrounding a barge used as the launch platform for a fireworks display. During the loading of the fireworks barge, during the transit of the fireworks barge to the display location, and until fifteen minutes prior to the start of the fireworks display, the restricted area encompasses the navigable waters around and under the fireworks barge within a radius of 100 feet. During the fifteen minutes preceding the fireworks display and during the fifteen minute fireworks display itself, the safety zone increases in size to encompass the navigable waters around and under the fireworks launch barge within a radius of 1,000 feet. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 9 a.m. on July 4, 2007, and will take place at Pier 50 in San Francisco. Towing of the barge from Pier 50 to the display location is scheduled to take place between 12 p.m. and 8 p.m. on July 4, 2007. During the fireworks display, scheduled to start at approximately 9:30 p.m. on July 4, 2007, the barge will be located approximately 600 feet off Wharf #5 in the Port of Redwood City in approximate position 37°30.35′ N, 122°12.85′ W.

(b) *Effective Period.* This section will be enforced from 9 a.m. to 10 p.m. on July 4, 2007. If the event concludes prior to the scheduled termination time, the Coast Guard will cease enforcement of the safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this safety zone by all vessels and persons is prohibited, unless specifically authorized by the Captain of the Port San Francisco, or his designated representative.

(d) *Enforcement.* All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, or the designated on-scene patrol personnel. Patrol personnel can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, Coast Guard Auxiliary, local, state, and federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The U.S. Coast Guard may be assisted in the patrol and enforcement of this safety zone by local law enforcement as necessary.

Dated: June 11, 2007.

W.J. Uberti,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. E7–12145 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–07–010]

RIN 1625–AA00

Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a permanent safety zone upon certain waters of the Patapsco River, Northwest Harbor, and Inner Harbor during the movement of the historic sloop-of-war USS CONSTELLATION, annually, on the Friday following Labor Day. This action is necessary to provide for the safety of

life on navigable waters during the tow of the vessel from its berth at the Inner Harbor in Baltimore, Maryland, to a point on the Patapsco River near the Fort McHenry National Monument and Historic Shrine in Baltimore, Maryland, and return. This action will restrict vessel traffic in portions of the Patapsco River, Northwest Harbor, and Inner Harbor during the event.

DATES: This rule is effective July 25, 2007.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–07–010 and are available for inspection or copying at Commander, U.S. Coast Guard Sector Baltimore, 2401 Hawkins Point Road, Building 70, Waterways Management Division, Baltimore, Maryland, 21226–1791 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Ronald Houck, at Coast Guard Sector Baltimore, Waterways Management Division, at telephone number (410) 576–2674 or (410) 576–2693.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 9, 2007, we published a notice of proposed rulemaking (NPRM) entitled ''Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD'' in the **Federal Register** (72 FR 17458). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

Each year, the USS CONSTELLATION Museum conducts a ''turn-around'' ceremony involving the sloop-of-war USS CONSTELLATION in Baltimore, Maryland on the Friday following Labor Day. The annual turning of the USS CONSTELLATION aids in the maintenance of the historic ship by ensuring even weathering of her hull. Planned events include a three-hour, round-trip tow of the CONSTELLATION in the Port of Baltimore, with an onboard salute with navy pattern cannon while the historic vessel is positioned off Fort McHenry National Monument and Historic Site. The historic sloop-of-war USS CONSTELLATION will be towed ''dead ship,'' which means that the vessel will be underway without the benefit of mechanical or sail propulsion. The return dead ship tow of the CONSTELLATION to its berth in the Inner Harbor is expected to occur immediately upon execution of a tug-assisted turn-around of the CONSTELLATION on the Patapsco River near Fort McHenry. The Coast Guard anticipates a large recreational boating fleet during this event, scheduled on a late Friday afternoon during the summer in Baltimore, Maryland. Operators should expect significant vessel congestion along the planned route.

The purpose of this rule is to promote maritime safety and protect participants and the boating public in the Port of Baltimore immediately prior to, during, and after the scheduled event. The rule will provide for a clear transit route for the participating vessels, and provide a safety buffer around the participating vessels while they are in transit. The rule will impact the movement of all vessels operating upon certain waters of the Patapsco River, Northwest Harbor and Inner Harbor.

Discussion of Comments and Changes

The Coast Guard received no comments on the proposed rule during the comment period published in the NPRM. No public meeting was requested and none was held. As a result, no change to the proposed regulatory text was made.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. This safety zone is a moving zone that will encompass only a small portion of the waterway. Vessels or persons may be able to transit safely around this zone.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to operate, remain or anchor within certain waters of the Patapsco River, Northwest Harbor and Inner Harbor, in Baltimore, Maryland, from 2 p.m. through 7 p.m. local time, annually, on the Friday following Labor Day. Because the zone is of limited size and duration, it is expected that there will be minimal disruption to the maritime community. Before the effective period, the Coast Guard will issue maritime advisories widely available to users of the river and harbors to allow mariners to make alternative plans for transiting the affected areas. In addition, smaller vessels not constrained by their draft, which are more likely to be small entities, may transit around the safety zone.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. We received no requests for assistance from any small entities.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. That paragraph applies because this rule establishes a safety zone.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.512 to read as follows:

§ 165.512 Safety Zone; Patapsco River, Northwest and Inner Harbors, Baltimore, MD.

(a) *Definitions.* For the purposes of this section:

(1) *Captain of the Port, Baltimore, Maryland* means the Commander, Coast Guard Sector Baltimore or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port, Baltimore, Maryland to act on his or her behalf.

(2) *USS CONSTELLATION ''turn-around'' participants* means the USS CONSTELLATION, its support craft and the accompanying towing vessels.

(b) *Location.* The following area is a moving safety zone: All waters, from surface to bottom, within 200 yards ahead of or 100 yards outboard or aft of the historic sloop-of-war USS CONSTELLATION, while operating in the Inner Harbor, the Northwest Harbor and the Patapsco River.

(c) *Regulations.* (1) The general regulations governing safety zones, found in § 165.23, apply to the safety zone described in paragraph (b) of this section.

(2) With the exception of USS CONSTELLATION ''turn-around'' participants, entry into or remaining in this zone is prohibited, unless authorized by the Captain of the Port, Baltimore, Maryland.

(3) Persons or vessels requiring entry into or passage through the moving safety zone must first request authorization from the Captain of the Port, Baltimore, Maryland to seek permission to transit the area. The Captain of the Port, Baltimore, Maryland can be contacted at telephone number (410) 576–2693. The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio VHF Channel 16 (156.8 MHz). Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the person or vessel shall proceed as directed. If permission is granted, all persons or vessels must comply with the instructions of the Captain of the Port, Baltimore, Maryland, and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State and local agencies.

(e) *Enforcement period.* This section will be enforced from 2 p.m. through 7 p.m. local time, annually, on the Friday following Labor Day.

Dated: June 14, 2007.

Brian D. Kelley,

Captain, U.S. Coast Guard, Captain of the Port, Baltimore, Maryland.

[FR Doc. E7–12246 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 07–023]

RIN 1625–AA00

Safety Zones; Lake Tahoe Fireworks, Lake Tahoe, CA.

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones in the navigable waters of Lake Tahoe for the loading, transport, and launching of fireworks to celebrate Independence Day. These safety zones are established to ensure the safety of participants and spectators. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zones without permission of the Captain of the Port or his designated representative.

DATES: This rule is effective from 8 a.m. on July 2, 2007 to 10 p.m. on July 5, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of the docket COTP San Francisco Bay 07–023 and are available for inspection or copying at Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California, 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 ext. 136.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Logistical details surrounding the event were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the event would occur before the rulemaking process was complete. Because of the dangers posed by the pyrotechnics used in this fireworks display, safety zones are necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

For the same reasons listed in the previous paragraph, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the pyrotechnics used in this fireworks display.

Background and Purpose

North Tahoe Business Association is sponsoring a fireworks display on July 3, 2007; Tahoe City Rotary is sponsoring a fireworks display on July 4, 2007; and Westshore Café is sponsoring a fireworks display on July 5, 2007 in the waters of Lake Tahoe. The fireworks displays are meant for entertainment purposes in celebration of Independence Day. These safety zones are being issued to establish a temporary regulated area in Lake Tahoe around the fireworks launch barge during loading of the pyrotechnics, during the transit of the barge to the display location, and during the fireworks display. These safety zones around the launch barge are necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barge. The Coast Guard has granted the event sponsor marine event permits for the fireworks displays.

Discussion of Rule

The Coast Guard is establishing temporary safety zones on specified waters of Lake Tahoe. During the loading of the fireworks barges, while the barges are being towed to the display location, and until the start of the fireworks display, the safety zones will apply to the navigable waters around and under the fireworks barges within a radius of 100 feet. Fifteen minutes prior to and during the fireworks displays, the area to which these safety zones applies to will increase in size to encompass the navigable waters around and under the fireworks barges within a radius of 1,000 feet.

Loading of the first pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 2, 2007, and will take place at Obexer's Boat Company, Homewood, California. Towing of the barge from Obexer's Boat Company to the display location is scheduled to take place between 9 a.m. and 11 a.m. on July 3, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 3, 2007, the fireworks barge will be located approximately 600–700 feet off of the shore line of King's Beach in position 39°14′00″ N, 120°01′50″ W.

Loading of the second pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 4, 2007, and will take place at Obexer's Boat Company, Homewood, California. Towing of the barge from Obexer's Boat Company to the display location is scheduled to take place between 9 a.m. and 2 p.m. on July 4, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 4, 2007, the fireworks barge will be located approximately 600–700 feet off of the shore line of Tahoe City in position 39°10′00″ N, 120°08′00″ W.

Loading of the third pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 5, 2007, and will take place at Obexer's Boat Company, Homewood, California. Towing of the barge from Obexer's Boat Company to the display location is scheduled to take place between 9 a.m. and 2 p.m. on July 5, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 5, 2007, the fireworks barge will be located approximately 600–700 feet off of the shore line of Homewood near Westshore Café in McKinney Bay in position 39°05′00″ N, 120°09′00″ W.

The effect of the temporary safety zones will be to restrict general navigation in the vicinity of the fireworks barges while the fireworks are loaded, during the transit of the fireworks barge, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the safety zones. These safety zones are needed to keep spectators and vessels a safe distance away from the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule restricts access to the waters encompassed by the safety zones, the effect of this rule will not be significant because the local waterway

users will be notified via public broadcast notice to mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule is not expected to have a significant economic impact on a substantial number of entities, some of which may be small entities. This rule may affect owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (i) Vessel traffic can pass safely around the area, (ii) vessels engaged in recreational activities and sightseeing have ample space outside of the effected portion of Lake Tahoe to engage in these activities, (iii) this rule will encompass only a small portion of the waterway for a limited period of time, and (iv) the maritime public will be advised in advance of these safety zones via public notice to mariners.

Assistance For Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions, options for compliance, or assistance in understanding this rule, please contact Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 ext. 136.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. Paragraph (34)(g) is applicable because this rule establishes a safety zone. A final ''Environmental Analysis Check

List'' and a final ''Categorical Exclusion Determination'' will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.35–T11–200 to read as follows:

§ 165.35–T11–200 Safety Zones; Lake Tahoe Fireworks Display, Lake Tahoe, CA.

(a) *Location.* These safety zones are established for the waters of Lake Tahoe surrounding barges used as the launch platform for fireworks displays to be held in celebration of Independence Day. During the loading of the fireworks barges, during the transit of the fireworks barges to the display location, and until fifteen minutes prior to the start of the fireworks display, the safety zone will encompass the navigable waters around and under the fireworks barges within a radius of 100 feet. During the fifteen minutes preceding the fireworks display and during the fireworks display, the safety zones will increase in size to encompass the navigable waters around and under the fireworks launch barge within a radius of 1,000 feet.

(1) Loading of the first pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 2, 2007, and will take place at Obexer's Boat Company, Homewood, California. Towing of the barge from Obexer's Boat Company to the display location is scheduled to take place between 9 a.m. and 11 a.m. on July 3, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 3, 2007, the fireworks barge will be located approximately 600–700 feet off of the shore line of King's Beach in position 39°14′00″ N, 120°01′50″ W.

(2) Loading of the second pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 4, 2007, and will take place at Obexer's Boat Company, Homewood, California. Towing of the barge from Obexer's Boat Company to the display location is scheduled to take place between 9 a.m. and 2 p.m. on July 4, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 4, 2007, the fireworks barge will be located approximately 600–700 feet off of the shore line of Tahoe City in position 39°10′00″ N, 120°08′00″ W.

(3) Loading of the third pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on July 5, 2007, and will take place at Obexer's Boat Company, Homewood, California. Towing of the barge from Obexer's Boat Company to the display location is scheduled to take place between 9 a.m. and 2 p.m. on July 5, 2007. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 5, 2007, the fireworks barge will be located approximately 600–700 feet off of the shore line of Homewood near Westshore Café in McKinney Bay in position 39°05′00″ N, 120°09′00″ W.

(b) *Effective period.* This section is effective from 8 a.m. on July 2, 2007, through 10 p.m. on July 5, 2007. If the event concludes prior to the scheduled termination time, the Coast Guard will cease enforcement of the safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this safety zone by all vessels and persons is prohibited, unless specifically authorized by the Captain of the Port San Francisco, or his designated representative.

(d) *Enforcement.* All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, or the designated on-scene patrol personnel. Patrol personnel can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, Coast Guard Auxiliary, local, state, and federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The U.S. Coast Guard may be assisted in the patrol and enforcement of these safety zones by local law enforcement as necessary.

Dated: June 11, 2007.

W.J. Uberti,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. E7–12139 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 07–020]

RIN 1625–AA00

Safety Zones; Lake Tahoe Independence Day Celebration, Lake Tahoe, CA and Lake Tahoe, NV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones in the navigable waters of Lake Tahoe for the loading, transport, and launching of fireworks to celebrate Independence Day. These safety zones are established to ensure the safety of participants and spectators. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zones without permission of the Captain of the Port or his designated representative.

DATES: This rule is effective from 5 a.m. on July 1, 2007, to 10:15 p.m. on July 4, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of the docket COTP San Francisco Bay 07–020 and are available for inspection or copying at Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 ext. 136.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Logistical details surrounding the event were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the event would occur before the rulemaking process was complete. Because of the dangers posed by the pyrotechnics used in this fireworks display, safety zones are necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

For the same reasons listed in the previous paragraph, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the pyrotechnics used in this fireworks display.

Background and Purpose

Red, White, and Tahoe Blue, Lake Tahoe Visitor's Authority, and Glenbrooks Fireworks Committee are sponsoring fireworks displays on July 4, 2007. These fireworks displays are meant for entertainment purposes in celebration of Independence Day. These safety zones are being issued to establish temporary regulated areas in Lake Tahoe around the fireworks launch barge during loading of the pyrotechnics, during the transit of the barges to the display locations, and during the fireworks displays. These safety zones around the launch barges are necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barges. The Coast Guard has granted each event sponsor a marine event permit for the fireworks display.

Discussion of Rule

The Coast Guard is establishing temporary safety zones on specified waters of Lake Tahoe. During the loading of the fireworks barges, while the barges are being towed to the display locations, and until the start of the fireworks displays, these safety zones will apply to the navigable waters around and under the fireworks barges within a radius of 100 feet. Fifteen minutes prior to and during the fireworks displays, the area to which these safety zones applies to will increase in size to encompass the navigable waters around and under the fireworks barges within a radius of 1,000 feet.

The first fireworks show is sponsored by Red, White, and Tahoe Blue and is in the waters of Lake Tahoe on Crystal Bay. Commencing at 5 a.m. on July 1, 2007, the barges will be towed from the shoreline of Incline Village, Nevada, to the display location, which is approximately 700 feet off the shore on Crystal Bay in position 39°14′06″ N, 119°57′53″ W. While the barges are in their display location they will be anchored and loaded from July 1, 2007, until July 4, 2007. The fireworks display is scheduled to commence at 9 p.m. on July 4, 2007 and last approximately thirty minutes.

The second fireworks show is being sponsored by Lake Tahoe Visitor's Authority and is in the waters of South Lake Tahoe. Loading of the pyrotechnics onto the fireworks barges is scheduled to commence at 8:30 a.m. on July 2, 2007, and will take place at Tahoe Keys Marina in South Lake Tahoe, California. Towing of the barges from Tahoe Keys Marina to the display location is scheduled to take place between 9:30 a.m. and 3 p.m. on July 4, 2007. During the fireworks display, scheduled to commence at approximately 9:45 p.m. on July 4, 2007, the fireworks barge will be located approximately 1,500 feet off of the shore line of South Lake Tahoe in position 38°57′56″ N, 119°57′21″ W. The fireworks display is scheduled to last approximately thirty minutes.

The third fireworks show is being sponsored by Glenbrooks Fireworks Committee. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 9 a.m. on July 3, 2007, and will take place at Obexers Marina in Homewood, California. Towing of the barge from Obexers Marina to the display location is scheduled to take place between 1 p.m. and 5 p.m. on July 3, 2007. The barge will be anchored overnight. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 4, 2007, the fireworks barges will be located approximately 600 feet off of the shore line of Glenbrook, Nevada on Glenbrook Bay in position 39°05′23″ N, 119°56′39″ W. The fireworks display is scheduled to last approximately eighteen minutes.

The effect of the temporary safety zones will be to restrict general navigation in the vicinity of the fireworks barges while the fireworks are loaded, during the transit of the fireworks barges, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the safety zones. These safety zones are needed to keep spectators and vessels a safe distance away from the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule restricts access to the waters encompassed by the safety zones, the effect of this rule will not be significant because the local waterway users will be notified via public broadcast notice to mariners to ensure the safety zones will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule is not expected to have a significant economic impact on a substantial number of entities, some of which may be small entities. This rule may affect owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (i) Vessel traffic can pass safely around the area, (ii) vessels engaged in recreational activities and sightseeing have ample space outside of the effected portion of Lake Tahoe to engage in these activities, (iii) this rule will encompass only a small portion of the waterway for a limited period of time, and (iv) the maritime public will be advised in advance of this safety zone via public notice to mariners.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions, options for compliance, or assistance in understanding this rule, please contact Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 ext. 136.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business

Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. Paragraph (34)(g) is applicable because this rule establishes a safety zone.

A final ''Environmental Analysis Check List'' and a final ''Categorical Exclusion Determination'' will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.35–T11–204 to read as follows:

§ 165.35–T11–204 Safety Zones; Lake Tahoe Independence Day Celebration, Lake Tahoe, CA, and Lake Tahoe, NV.

(a) *Location.* These safety zones are established for the waters of Lake Tahoe surrounding barges used as the launch platform for fireworks displays to be held in celebration of Independence Day. During the loading of the fireworks barge, during the transit of the fireworks barges to the display locations, and until fifteen minutes prior to the start of the fireworks displays, the safety zones will encompass the navigable waters around and under the fireworks barges within a radius of 100 feet. During the fifteen minutes preceding the fireworks displays and during the fireworks displays, the safety zones increases in size to encompass the navigable waters around and under the fireworks launch barges within a radius of 1,000 feet.

(1) The first fireworks show is in the waters of Lake Tahoe on Crystal Bay. Commencing at 5 a.m. on July 1, 2007, the barges will be towed from the shoreline of Incline Village, Nevada, to the display location, which is approximately 700 feet off the shore on Crystal Bay in position 39°14′06″ N, 119°57′53″ W. While the barges are in their display location they will be anchored and loaded from July 1, 2007, until July 4, 2007. The fireworks display is scheduled to commence at 9 p.m. on July 4, 2007 and last approximately thirty minutes.

(2) The second fireworks show is in the waters of South Lake Tahoe.

Loading of the pyrotechnics onto the fireworks barges is scheduled to commence at 8:30 a.m. on July 2, 2007, and will take place at Tahoe Keys Marina in South Lake Tahoe, California. Towing of the barges from Tahoe Keys Marina to the display location is scheduled to take place between 9:30 a.m. and 3 p.m. on July 4, 2007. During the fireworks display, scheduled to commence at approximately 9:45 p.m. on July 4, 2007, the fireworks barge will be located approximately 1,500 feet off of the shore line of South Lake Tahoe in position 38°57′56″ N, 119°57′21″ W. The fireworks display is scheduled to last approximately thirty minutes.

(3) The third fireworks show is in the waters of Lake Tahoe on Glenbrook Bay. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 9 a.m. on July 3, 2007, and will take place at Obexers Marina in Homewood, California. Towing of the barge from Obexers Marina to the display location is scheduled to take place between 1 p.m. and 5 p.m. on July 3, 2007. The barge will be anchored overnight. During the fireworks display, scheduled to commence at approximately 9:30 p.m. on July 4, 2007, the fireworks barge will be located approximately 600 feet off of the shore line of Glenbrook, Nevada on Glenbrook Bay in position 39°05′23″ N, 119°56′39″ W. The fireworks display is scheduled to last approximately eighteen minutes.

(b) *Effective Period.* This section will be enforced from 5 a.m. on July 1, 2007, to 10:15 p.m. on July 4, 2007. If the event concludes prior to the scheduled termination time, the Coast Guard will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within these safety zones by all vessels and persons is prohibited, unless specifically authorized by the Captain of the Port San Francisco, or his designated representative.

(d) *Enforcement.* All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, or the designated on-scene patrol personnel. Patrol personnel can be comprised of commissioned, warrant, and petty officers of the Coast Guard onboard Coast Guard, Coast Guard Auxiliary, local, state, and federal law enforcement vessels. Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The U.S. Coast Guard may be assisted in the patrol and enforcement of these safety zones by local law enforcement as necessary.

Dated: June 13, 2007.

W.J. Uberti,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

[FR Doc. E7–12281 Filed 6–20–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket No. FEMA–7979]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: *Effective Dates:* The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

ADDRESSES: If you want to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office.

FOR FURTHER INFORMATION CONTACT: David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

In addition, FEMA has identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region III				
Virginia: Culpeper, Town of, Culpeper County	510042	June 16, 1975, Emerg, March 2, 1989, Reg, June 18, 2007, Susp.	June 18, 2007 ..	June 18, 2007.
Region VIII				
Utah:				
Bountiful, City of, Davis County	490039	July 19, 1973, Emerg, September 29, 1978, Reg, June 18, 2007, Susp.	.....do	Do.
Centerville, City of, Davis County	490040	July 24, 1975, Emerg, March 1, 1982, Reg, June 18, 2007, Susp.	.....do	Do.
Clearfield, City of, Davis County	490041	November 7, 1974, Emerg, February 20, 1979, Reg, June 18, 2007, Susp.	.....do	Do.
Davis County, Unincorporated Areas	490038	April 22, 1975, Emerg, March 1, 1982, Reg, June 18, 2007, Susp.	.....do	Do.
Farmington, City of, Davis County	490044	May 13, 1975, Emerg, August 17, 1981, June 18, 2007, Susp.	.....do	Do.
Fruit Heights, City of, Davis County	490045	May 11, 1977, Emerg, August 17, 1981, Reg, June 18, 2007, Susp.	.....do	Do.
Kaysville, City of, Davis County	490046	April 18, 1975, Emerg, March 1, 1982, Reg, June 18, 2007, Susp.	.....do	Do.
Layton, City of, Davis County	490047	December 13, 1974, Emerg, December 1, 1982, Reg, June 18, 2007, Susp.	.....do	Do.
North Salt Lake, City of, Davis County	490048	May 30, 1975, Emerg, August 29, 1978, Reg, June 18, 2007, Susp.	.....do	Do.
South Weber, City of, Davis County	490049	November 8, 1974, Emerg, September 12, 1978, Reg, June 18, 2007, Susp.	.....do	Do.
Sunset, City of, Davis County	490050	March 11, 1975, Emerg, November 21, 1978, Reg, June 18, 2007, Susp.	.....do	Do.
West Bountiful, City of, Davis County ...	490052	July 2, 1975, Emerg, August 3, 1981, Reg, June 18, 2007, Susp.	.....do	Do.
Woods Cross, City of, Davis County	490054	June 12, 1975, Emerg, August 29, 1978, Reg, June 18, 2007, Susp.	.....do	Do.

*do = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: June 12, 2007.

Michael K. Buckley,

Deputy Assistant Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. E7–12207 Filed 6–22–07; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 0612242865–7168–01; I.D. 092506A]

RIN 0648–AU90

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS revises regulations implementing the Atlantic Large Whale Take Reduction Plan (ALWTRP) by expanding the Southeast U.S. Restricted Area and modifying regulations pertaining to gillnetting within the Southeast U.S. Restricted Area. NMFS prohibits gillnet fishing or gillnet possession during annual restricted periods associated with the right whale calving season. Limited exemptions to the fishing prohibitions are provided for gillnet fishing for sharks and for Spanish mackerel south of 29°00′ N. lat. An exemption to the possession prohibition is provided for transiting through the area if gear is stowed in accordance with this final rule. This action is required to meet the goals of the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA). This action is necessary to protect northern right whales from serious injury or mortality from entanglement in gillnet gear in their calving area in Atlantic Ocean waters off the Southeast U.S.

DATES: This final rule is effective July 25, 2007.

ADDRESSES: Requests for copies of this final rule should be addressed to Chief, Marine Mammal Branch, Attn: Right Whale Gillnet Rule, Protected Resources, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701. Copies of the Environmental Assessment (EA), Final Regulatory Flexibility Analysis (FRFA), and copies of all citations referenced in this final rulemaking may be obtained from the persons listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Laura Engleby, 727–824–5312, Barb Zoodsma, 904–321–2806, or Nancy Young, 727–824–5607.

Electronic Access: Regulations, compliance guides, and background documents for the ALWTRP can be downloaded from the ALWTRP web site at *http://www.nero.noaa.gov/whaletrp/*.

SUPPLEMENTARY INFORMATION:

Background

NMFS published a proposed rule on November 15, 2006 (71 FR 66482), to permanently prohibit gillnet fishing in portions of the Southeast U.S. to protect right whales from entanglement in gillnet gear during their annual calving season. The proposed rule included prohibitions on gillnet fishing and possession, with some exemptions. A detailed description of the proposed management measures and supporting background information and analysis is included in the proposed rule (71 FR 66482, November 15, 2006).

NMFS would like to highlight that this action removes the definitions of ''Shark gillnetting,'' ''Strikenet or to fish with strikenet gear,'' and ''To strikenet for sharks'' from 50 CFR 229.2. The revised ALWTRP regulations are based on gear characteristics, and NMFS believes the regulations do not need to rely on these definitions.

NMFS requested public comment on the proposed rule and provided a 30 day public comment period. NMFS received requests from the public to extend the comment period, and on January 16, 2007, NMFS published a notice in the **Federal Register** reopening the comment period for an additional 15 days (72 FR 1689). In that notice, NMFS announced that all comments received during the period November 15, 2007, through January 31, 2007, would be considered in this rulemaking. Below, we summarize the public comments received, our responses to those comments, and a change made to the proposed regulations based on the comments.

Comments on the Notice of Proposed Rulemaking and Responses

NMFS received 4,571 comments on the proposed rule from fishery management agencies and commissions of southeastern U.S. states, the Marine Mammal Commission (MMC), environmental organizations, commercial fishing organizations, commercial and recreational fishermen, and interested members of the public. NMFS received these comments in the form of electronic mail, letters, and facsimile. Of those, 4,544 were identical, or slightly modified, form letters expressing support for the proposed rule, and 27 contained substantive comments on specific measures or components of the proposed rule. NMFS did not receive any comments on the removal of strikenet definitions. In the text below, NMFS provides a summary of the comments, recommendations, and issues raised that relate to the measures in this rulemaking, provides responses to them, and identifies changes to the proposed regulations. Comments not relevant to this rulemaking, such as those pertaining to the February 16, 2006, temporary rule; the November 15, 2006, emergency rule; and process-related comments relative to the ALWTRT's Southeast (SE) Subgroup meeting were read and considered but are not being discussed in this document addressing the proposed and final rule.

Comment 1: Several commenters stated that gillnet fishing gear is dangerous to right whale mothers and calves. These commenters urged that the proposed rule be finalized, citing the right whale's extremely low abundance estimates and stating that the loss of even one animal contributes to the risk of extinction. Several of these commenters indicated that the loss of right whales has implications throughout the ecosystem. Others emphasized that it is NMFS' responsibility to protect this species and prevent its extinction.

Response: NMFS agrees that gillnet fishing gear can be dangerous to right whale calves, as demonstrated by the January 22, 2006, right whale calf mortality, which occurred as a result of entanglement in gillnet gear allowed to be used in the Southeast U.S. Restricted Area during the restricted period. NMFS also agrees that estimates of right whale abundance are low, that the loss of one right whale may potentially have implications for the right whale population and its ecosystem (see response to Comment 2), and that NMFS has a responsibility to protect right whales. The purpose of this final rule is to protect right whales from the threat of entanglement in gillnet gear by implementing, with revisions, existing ALWTRP regulations promulgated in 1997 under the MMPA that require the Assistant Administrator for Fisheries (AA) to close the Southeast U.S. Restricted Area to gillnet gear during the annual restricted period unless the AA

revises the restricted period or implements other measures under 50 CFR 229.32(g)(2).

Comment 2: One commenter stated that concerns for the status of the right whale are unwarranted and population figures are not valid based on his calculations of right whale abundance using a variety of variables (e.g., abundance in 1935, sex ratio, calving interval, age at senescence), and requested information upon which NMFS' population estimates were based. The commenter also questioned the role of fishing interactions as one of the causes of the right whale's reduced population.

Response: NMFS relies on the best available scientific information, including peer-reviewed scientific literature, to assess northern right whale abundance, status, and threats in marine mammal Stock Assessment Reports (SAR), required by provisions of the MMPA. The SAR for northern right whales in the North Atlantic is updated annually and reviewed both internally and externally by teams of scientific experts. The 2006 SAR for northern right whales in the North Atlantic (Waring *et al.*, 2007) indicates that the best estimate of minimum population size for the species is 306 individually-recognized whales known to be alive during 2001. Because the data are from identification photographs and genetic samples in all known right whale aggregation areas, and very few new adult whales have been added since the mid–1990s, NMFS believes that these records represent a nearly complete census of the population. Therefore, NMFS does not rely on life history parameters to estimate right whale abundance and disagrees that the population figures quoted in the proposed rule are invalid.

Additional population analyses and modeling exercises have been conducted and published in the peer-reviewed literature (e.g., Caswell *et al.*, 1999; Fujiwara and Caswell, 2001). These studies cite high mortality rates in the 1980s and 1990s and conclude that the population began to decline in the early 1990s. These studies conclude that preventing the death of even one adult female could significantly affect the population's trend. A 2001 evaluation by the International Whaling Commission's (IWC) Scientific Committee (Best *et al.*, 2001) also concluded that the population of northern right whales in the North Atlantic is not likely much greater than 300 individuals.

As a result of the low population size, the lack of observed population growth, and deaths from human activities, NMFS determined in 2000 and each year since that the MMPA-defined ''Potential Biological Removal'' (i.e., the maximum number of individuals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its Optimum Sustainable Population (OSP)) for northern right whales in the North Atlantic is zero. That is, the population cannot sustain any deaths or serious injuries due to human causes for the species to recover. Therefore, NMFS disagrees that concerns for the right whale population size are unwarranted.

With regard to the role of fishing interactions as one of the true causes of the reduced population, NMFS acknowledges that by 1935, the northern right whale population was severely depleted by commercial whaling. However, the second-leading known cause of death in right whales from 1970 to 2005 is entanglement in fishing gear. Consequently, the current right whale recovery plan states that implementation of strategies to reduce the likelihood of entanglement is an action that must be taken to prevent extinction or to prevent the species from declining irreversibly (NMFS, 2005).

In sum, NMFS believes that the status of right whales has not improved since the promulgation of the ALWTRP in 1997 and that implementing this provision of the ALWTRP, with revisions, is warranted and necessary for the protection and conservation of right whales.

Comment 3: One commenter questioned whether the January 22, 2006, right whale mortality was the result of entanglement in gillnet gear. The commenter stated that NMFS initially reported to local media that the preliminary cause of death was ship strike, the immediate cause of death was never determined by the necropsy team, and the more typical causes of death from entanglement (e.g., infection, dehydration, or drowning) were not found in this case. The commenter also stated that the lead necropsy scientist reported that the scars on the whale were healing (i.e., the whale could not have been killed by recent entanglement), and that no gear was retrieved from the animal. The commenter further stated that NMFS falls short of satisfying the evidentiary requirements for implementing 50 CFR 229.32(g)(1).

Response: NMFS disagrees that staff reported to local media the January 22, 2006, right whale calf mortality was the result of ship strike. However, NMFS is aware that, shortly following the necropsy, one media outlet erroneously quoted NMFS as stating the cause of death was a ship strike, and recently, the erroneous report was repeated by a second media outlet. In both instances, NMFS contacted the media outlets to correct the inaccuracy.

NMFS acknowledges that the necropsy team did not determine the immediate cause of death of the right whale calf (e.g., infection, dehydration). Internal organs had autolyzed significantly by the time the animal was necropsied. However, the final necropsy report stated the following with regard to the pre-mortem net entanglement injuries: ''the most parsimonious hypothesis is that these injuries were sufficiently serious to initiate the demise of'' this right whale. Thus, the necropsy report supported NMFS' determination that the right whale calf was seriously injured and ultimately died as a result of entanglement in gillnet gear.

NMFS also acknowledges that healing processes had initiated in the peduncle lesions created by net entanglement. Normal live tissue responds immediately to injuries by initiating the healing process. For example, coagulation (''healing'') stops uncontrolled blood flow and similarly, tissue undergoes changes (''healing'') in an attempt to repair injuries. However, it is important not to confuse the process of ''healing'' (an injury yet to be repaired) with an animal's ability to successfully complete the healing process (reparation). In the case of the right whale calf, the animal's body was in the process of attempting to repair (healing) its wounds; however, it was unsuccessful at repairing its entanglement injuries prior to succumbing to death.

Finally, NMFS also acknowledges that gillnet gear was not found on the dead right whale calf. However, evidence of recent entanglement was clearly documented by the necropsy team. Entanglement-related damage to the animal's peduncle included ''extensive epidermal and dermal indentation and penetration with overall pattern formation of diamond, vee, and straight lines....'' Images of these lesions were presented at an informal orientation workshop conducted for interested participants prior to the formal SE Subgroup meeting. At least one gillnet fisherman present stated that the lesions were very similar to gillnet lesions observed on rays incidentally taken in gillnet during his fishing operations. The damage to the animal that was judged to be the result of entanglement met NMFS' criteria of a serious injury (i.e., an injury likely to result in mortality (50 CFR 216.3)). Therefore,

NMFS disagrees with the commenter that NMFS falls short of evidentiary requirements for implementing 50 CFR 229.32(g)(1) since NMFS has determined, based on best available information and discussions with scientific investigators, that the right whale's entanglement and serious injury by gillnet gear ultimately led to the death of the animal (see also responses to comments 4, 5, and 6).

Comment 4: One commenter stated that the proposed rule does not reflect the fishing industry's belief that illegal fishing gear used in the Southeast U.S. Restricted Area was likely involved in the interaction. The commenter stated that there was no clear evidence that legal gear used in the Southeast U.S. Restricted Area was the primary cause of death of the right whale calf found dead on January 22, 2006. The commenter also stated that NMFS ignored information provided by the fishing industry at the SE Subgroup meeting that an illegal gillnet operation was cited by the U.S. Coast Guard in the same area and time as the whale mortality event.

Response: NMFS Office of Law Enforcement has actively investigated the January 22, 2006, right whale mortality, as well as gillnet fishing operations occurring in the same general time and area. As a matter of enforcement policy, NMFS does not provide information on alleged violations of fishery regulations prior to the issuance of charges or if no charges are filed. However, NMFS affirms that we have actively considered the information presented by the fishing industry regarding potential illegal fishing in developing both the proposed and this final rule and that there is no substantiated evidence indicating that illegal gear was involved in the entanglement of the right whale calf.

The April 2006 SE Subgroup meeting Key Outcomes Document (Ellenberg Associates, Inc., 2006) does reflect that some attendees questioned whether legal or illegal fishing caused the right whale mortality. NMFS learned during the Subgroup meeting that there was some confusion among fishermen as to the legality of 4–7/8 inch (12.4 cm) stretched mesh gillnet being used in the restricted area during the restricted period, and, according to the fishermen, this gear was being used in the area where the whale calf was found. One of the industry statements captured in the Key Outcomes Document under Individual Comments reflects this confusion: ''Industry knows what happened with this calf: Fishermen suspect the entanglement involved 4–7/8 inch stretched mesh gillnet.'' However, fishing 4–7/8 inch (12.4 cm) stretched mesh gillnet was allowed under ALWTRP regulations in the Southeast U.S. Restricted Area during the restricted period.

The actual gear entangling the calf was never recovered and the mesh size of the gillnet gear involved in the entanglement could not be determined. Various mesh sizes were legally used within the area, subject to different restrictions established under the ALWTRP regulations, fishery management plans, and applicable state authorities. Even if the actual gear used was 4–7/8 inch (12.4 cm) stretch mesh, as asserted by industry at the SE Subgroup meeting, that gear type was allowed to be used under ALWTRP regulations.

Scientists conducting right whale aerial surveys during the weeks preceding the discovery of the dead right whale calf documented large numbers of buoys in Federal waters off the mouth of the St. Johns River. On-water scientists studying right whales reported and photographed fishermen hauling back large amounts of gillnet that were attached to the buoys. These observations were reported at the SE Subgroup meeting and included in the meeting's Key Outcomes Document (Ellenberg Associates, Inc. 2006) This fishing effort was in the vicinity of where the calf's carcass was found. It was also in an area that included a high density of right whale sightings, including the right whale calf prior to its death. NMFS asked right whale scientists conducting research in the area to report any activity that they felt might be a threat to right whales. No other fishing activity of concern in NE Florida or SE Georgia at that time was reported to NMFS.

NMFS and its law enforcement partners strive to ensure compliance and detect violations. In this case, a large amount of legal fishing with gillnet gear was occurring in the time and place of the right whale calf's entanglement and death. NMFS has considered and investigated the information presented by the fishing industry at the SE Subgroup meeting. NMFS continues to believe, consistent with its previous determinations under 50 CFR 229.32(g)(1), that the death of the right whale calf was the result of entanglement in gillnet gear allowed to be used in the Southeast U.S. Restricted Area during the restricted period.

Comment 5: One commenter stated that NMFS failed to identify the specific fishery involved in the January 22, 2006, right whale calf mortality event. This commenter stated that there was no evidence the North Carolina whiting gillnet fishery was involved in the alleged entanglement.

Response: The implementing regulations do not require NMFS to identify the specific fishery involved; rather, NMFS must determine that the entanglement was caused by gillnet gear allowed to be used in the Southeast U.S. Restricted Area during the restricted period. See response to Comments 3 and 6 regarding NMFS' determinations that gillnet gear was involved in the entanglement and that the gear was set within the Southeast U.S. Restricted Area, respectively. The restricted period at the time was from November 15 to March 31. The calf was sighted on December 30, 2005, and no linear lesions were evident. However, on January 8, 2006, aerial photographs taken of the calf reveal that the peduncle linear lesions were present. Therefore, the entanglement must have occurred between those two dates and during the restricted period.

Comment 6: One commenter stated there was no scientific evidence that the gear implicated in the January 22, 2006, right whale mortality event was actually set in the Southeast U.S. Restricted Area. This commenter stated that gear could have been from outside the Southeast U.S. Restricted Area and pointed out that entangled whales often travel great distances.

Response: The New England Aquarium's right whale photograph database was consulted to determine the sighting history for the dead calf. On December 30, 2005, the calf and its mother were sighted together off St. Catherines Island, Georgia. The calf did not show evidence of entanglement at the time. On January 8 and 9, 2006, the pair were sighted off the mouth of Nassau Sound, Florida, and Cumberland Sound, Georgia, respectively. At that time, the aerial survey photographs suggested the calf had linear scars, consistent with some type of entanglement event. Both sightings occurred well within the Southeast U.S. Restricted Area (the Georgia and Florida sighting locations were greater than 30 nm (55.6 km) and 70 nm (129.6 km), respectively, from the nearest boundary of the Southeast U.S. Restricted Area). Since mother-calf pairs typically remain on the calving grounds in January and are unlikely to travel very long distances in a short period of time, NMFS believes the calf became entangled in gillnet gear within the Southeast U.S. Restricted Area.

Comment 7: One commenter stated that NMFS did not adequately consider the alternative fishing restrictions proposed by gillnet fishermen at the SE Subgroup meeting that would allow

gillnet fishing for whiting to continue north of 29° N. lat. The commenter then listed the restrictions proposed at the SE Subgroup meeting, and included the following additional fishing restrictions: (1) 600 pound (272.4 kg) weak links, (2) all gear would be hauled back one hour before sunset, and (3) cooperative research. The commenter stated these proposed restrictions were similar to those being proposed in the exemption for the Spanish mackerel fishery, but NMFS disregarded the North Carolina whiting fishermen's proposal. The commenter also stated that, unlike the fishing industry proposal, NMFS fully considered comments from the MMC.

Two other commenters stated that they did not support the alternative fishing restrictions proposed by the commercial fishing industry, stating that the proposed measures do not reduce risk inherent in the gear type and do not address the threat to newborn calves in that area.

Response: NMFS explicitly considered the specific alternative gillnet restrictions proposed by the fishermen at the SE Subgroup meeting. The fishermen's proposal was included in the Key Outcomes Document (Ellenberg Associates, Inc., 2006) and was analyzed in the EA as Alternative 2. However, NMFS determined neither the operational restrictions proposed by the commenter, nor any other operational restrictions, would provide sufficient reduction in the likelihood of gillnet gear interactions with right whales, or reduce the risk of right whale serious injury and mortality in the Southeast U.S. Restricted Area. The proposed restrictions would allow large amounts of net to be in the water for long periods of time (i.e., long soak time) in the core right whale calving area.

NMFS considered the three additional fishing restrictions proposed by the commenter (see comment above). First, it is unknown whether weak links will release very young calves. Second, NMFS acknowledges that hauling back gear prior to sunset would likely result in risk reduction. However, the potential for right whale interactions with gillnets in a substantial and core portion of the right whale calving area would not be eliminated during the calving season because large amounts of net and vertical line with very long soak times would continue to be used in the Southeast U.S. Restricted Area. Third, cooperative research does not in and of itself reduce risk to right whales. Therefore, NMFS has determined that these newly proposed restrictions do not meet the bases in 50 CFR 229.32(g)(2) under which exemptions to a full, permanent closure of the restricted area are allowable.

NMFS disagrees that the whiting gillnet proposal for fishing north of 29° N. lat. is similar to the Spanish mackerel exemption. Right whale distribution patterns south of 29° N. lat. and existing state gillnet prohibitions combine to result in minimal spatial and temporal overlap of right whales and Spanish mackerel fishing effort during the exempted periods. All gillnet fishing, including Spanish mackerel fishing, is prohibited north of 29° N. lat. by this final rule because any gillnet fishing activity in that area during the calving season would result in heavy spatial and temporal overlap with calving right whales. For the minimal amount of time that right whales and Spanish mackerel fishing effort do overlap south of 29° N. lat., the fishing gear characteristics and operational methods reduce risk to right whales: nets greater than 800 yards (2,400 ft, 732 m) are prohibited and soak time must be less than one hour. The whiting fishermen proposal would allow nets up to 2,800 yards (8,400 ft, 2.56 km) in length (2,000 more yards (6,000 ft, 1.83 km) of net and associated vertical lines than allowed by the Spanish mackerel exemption) and soak times of 4–6 hours (Ellenberg Associates, Inc. 2006).

NMFS considered comments submitted by the MMC. Title II of the MMPA charges the MMC with recommending to Federal officials steps the MMC deems necessary or desirable for the protection and conservation of marine mammals. The MMPA charges Federal officials with responding to the MMC regarding their recommendations. As such, NMFS is required to consider MMC recommendations. As part of this rulemaking, NMFS has considered the MMC recommendations, similar to other recommendations, relative to 50 CFR 229.32(g)(1) and (2).

Comment 8: One commenter stated that the actions contained in the proposed rule are beyond the scope of the authority of the NMFS Southeast Regional Office (SERO).

Response: The regulations at 50 CFR 229.32(g)(1) state that the AA must take specific action when a serious injury or mortality of a right whale occurs in the Southeast U.S. Restricted Area from November 15 through March 31 as a result of entanglement by gillnet gear allowed to be used in that area and time. NMFS is required to close that area to that gear type for the rest of that time period and for that same time period in each subsequent year, unless the AA revises the restricted period or unless other measures are implemented in accordance with 50 CFR 229.32(g)(2). The January 22, 2006, right whale calf mortality occurred as a result of entanglement in gillnet gear allowed to be used in the Southeast U.S. Restricted Area during the restricted period (see responses to Comments 3, 4, 5, and 6). Consequently, the AA determined to take action through this final rule to prevent additional serious injury or mortalities of right whales. Thus, NMFS has appropriately implemented its authority.

Comment 9: One commenter stated that the provisions required for the exemption of gillnetting for sharks and for Spanish mackerel south of 29° N. lat., including restrictions on setting nets within 3 nm (5.6 km) of right whales and other large whales and requiring the removal of nets from the water if a whale approaches within 3 nm (5.6 km), may be difficult to put into practice and impossible to enforce, given that the exemptions occur in areas for which there are no dedicated marine mammal surveys and the likelihood that fishermen would receive notification of whales in the area would be small. The commenter suggests continued research on methodology, such as passive acoustic monitoring, for determining that no whales are in the vicinity of nets in the water.

Response: NMFS acknowledges these provisions may be challenging to enforce, but we believe other requirements for the exempted fisheries will allow fishermen to detect and avoid close interactions with large whale species. For example, fishermen gillnetting for sharks in the restricted area are required to use a spotter plane (50 CFR 229.32(f)(4)(iv)), so whales in the area will likely be seen and fishermen will be capable of removing gear from the water. The Spanish mackerel fishery has existing gear requirements at 50 CFR 622.41(c)(3)(ii), including short soak time, limit of one net fished, set, or placed in the water at any one time, and restrictions on float line length, as well as new requirements prohibiting the setting of gear at night or in low visibility and removing gear from the water before night or if visibility decreases below 500 yards (1,500 ft, 460 m). NMFS believes these factors, in conjunction with known and predicted right whale distribution patterns in the Southeast U.S. Restricted Area south of 29° N. lat. during December through March, and existing Florida regulations prohibiting gillnetting in state waters that further reduce the potential spatial overlap between gillnet fishing and right whales, are operationally effective and will protect right whales from the risk of serious injury and mortality.

NMFS agrees that methods such as passive acoustic monitoring may be useful for managing human interactions with whales. However, at this time it is unknown if mother/calf pairs vocalize while in the Southeast U.S. calving area. Research in this area is underway. For example, hydrophone arrays were deployed during the 2006–2007 calving season in the vicinity of the St. Mary's and Brunswick River entrances. Researchers will soon begin examining the findings and comparing them to aerial survey sightings to determine the efficacy of this technology in reliably detecting the presence of whales, including mother/calf pairs, in the Southeast U.S. calving area.

Comment 10: NMFS received several comments regarding the economic impact of the proposed rule. One commenter stated that the proposed regulations disproportionately impact North Carolina gillnetters targeting whiting and stated that these fishermen are not being provided with a safe, viable economic alternative to continue fishing for whiting in the region. Other commenters stated that while the rule may impose a burden on some gillnetters, economic interests should not supersede necessary species protection, and fishing operations must be restricted to reduce entanglement risk to endangered right whales.

Response: As required by the Regulatory Flexibility Act (RFA), NMFS conducted an analysis of the socio-economic impacts of these regulations, which can be found in the EA and regulatory flexibility analysis. NMFS agrees that this final rule is expected to most greatly affect fishermen who fish for whiting in the Southeast U.S. Restricted Area North. NMFS notes, however, that all gillnet fishing will be prohibited by this final rule in the Southeast U.S. Restricted Area North, not just whiting fishing. In addition, comments made by whiting fishermen at the SE Subgroup meeting suggest these losses could be mitigated by moving into other areas and/or targeting other species at other times of the year, resulting in minimal long-term impacts for these fishermen from this final rule. Finally, at the SE Subgroup meeting, NMFS inquired about the feasibility of fishing for whiting in other areas, such as the Southeast U.S. Restricted Area South, but fishermen reported that a unique habitat feature off northeast Florida resulted in a very localized concentration of whiting and this is where whiting gillnet fishing effort was necessarily focused.

This final rule implements regulations at 50 CFR 229.32(g)(1), with associated revisions to 50 CFR 229.32(f). Consequently, anything less than a full and permanent closure of the Southeast U.S. Restricted Area to all gillnet fishing during the restricted period can only be authorized based on the considerations in 50 CFR 229.32(g)(2). This final rule eliminates the potential for right whale interactions with gillnets in the Southeast U.S. Restricted Area North, a substantial and core portion of the right whale calving area. However, this final rule does allow for gillnet fishing exemptions in the Southeast U.S. Restricted Area South. NMFS has determined that a combination of existing and new regulatory requirements for exempted fisheries in this area and during the restricted period are both operationally effective and capable of protecting right whales from the risk of serious injury and mortality pursuant to 50 CFR 229.32(g)(2)(i) (see also response to Comment 7).

Comment 11: One commenter stated that there is no evidence that low-rise North Carolina-style whiting gear or associated vertical lines presents a serious threat to right whales in the Southeast U.S. Restricted Area.

Response: Although the exact mechanism by which right whales become entangled in gillnet gear is unknown, NMFS has documented entanglements of right whales in gillnets and vertical lines. Therefore, NMFS cannot verify that gillnets fished in a low-rise fashion (i.e., sink gillnet) are less risky than other gillnets or gear with vertical lines in the core calving area. Therefore, fishing with low-rise gillnets in the Southeast U.S. Restricted Area North does not meet the bases in 50 CFR 229.32(g)(2) under which exemptions to a full, permanent closure of the restricted area are allowable.

Comment 12: Comments were received regarding the proposed changes to the boundaries of the Southeast U.S. Restricted Area. Several commenters supported expanding the restricted area to include waters off South Carolina, and several other commenters requested further expansion. Two commenters supported a boundary of 40 nm (74.08 km) off the coast of South Carolina, with one commenter citing habitat analysis research that indicates potential right whale habitat extends in excess of 35 nm (64.82 km) from the South Carolina shoreline. Two other commenters advocated expanding the entire Southeast U.S. Restricted Area to 200 nm (370.4 km) (the outer limit of the U.S. Exclusive Economic Zone (EEZ)), with one commenter citing low survey effort in offshore waters and uncertainty about use of these waters by whales, and reasoning that extending the geographical boundary would have no significant economic impact and would prevent development of new fisheries in that area.

Another commenter opposed the expansion of the restricted area, stating that the expansion is not based on credible science. The commenter stated that NMFS based its decision on aerial surveys conducted from 2001–2005, with no entanglements or strandings to indicate there is a problem in this area, a single observation of a right whale mother/calf pair in the 2004–2005 calving season, and a single year of acoustic monitoring. The commenter requested that more substantial and robust scientific evidence justifying the expansion be presented.

Response: The decision to expand the Southeast U.S. Restricted Area to include waters off South Carolina is based on several factors, which are described in the proposed rule (71 FR 66482, November 15, 2006) and EA. These factors include aerial and acoustic monitoring data that show the consistent occurrence of right whales in waters off South Carolina throughout the winter months (McLellan *et al.*, 2001; Glass *et al.*, 2005; Clark 2006).

During relatively limited aerial survey effort from 2001–2005, NMFS contractors documented numerous sightings of right whales off South Carolina during the calving season. NMFS consulted aerial survey data collected off South Carolina during the 2005/2006 and 2006/2007 calving season to determine if right whales were continuing to use that area. At least 25 sightings of one or more right whales, including mother/calf pairs, were observed off South Carolina during each of those calving seasons (Glass and Taylor 2006; and Wildlife Trust, unpub. data). One mother/calf pair was observed off South Carolina multiple times but was not observed during that calving season in any other survey area. Thus, the best available information indicates South Carolina is used exclusively as a calving area by some right whales.

NMFS also relied on habitat models that demonstrate a strong relationship between the spatial distribution of calving right whales and specific environmental variables (i.e., water temperature and bathymetry). Environmental conditions strongly correlated with calving right whale distribution are typically found off South Carolina to distances of 35 nm (64.82 km) from shore during winter months. Thus, NMFS is expanding the Southeast U.S. Restricted Area to include waters 35 nm (64.82 km) off the

coast of South Carolina to adequately protect right whales from the threat of entanglement in fishing gear during the calving season.

NMFS specifically solicited public comment on the decision to place the boundary at 35 nm (64.82 km) rather than 40 nm (74.08) off the coast of South Carolina. Although NMFS considered various factors, including Hain and Kenney's (2005) conclusion that uncertainty in predicting right whale occurrence is increased with distance from shoreline due to reduced search effort, we believe that scientific evidence does not support a 40 nm (74.08 km) boundary. Recent predictive modeling efforts show that the expected seasonal progression of temperature off South Carolina is such that the optimal water temperature/bathymetry correlates preferred by right whales, and peak predicted sighting rates, for calving right whales occurs throughout much of the spatial range in waters typically out to 50 km (27 nm) from shore (Garrison, 2007). However, habitat in the marine environment is best represented as a spatial gradient between the most suitable and least suitable environments, and there is no clear spatial boundary for the habitat and no boundary to the movement of right whales inside and outside of the optimal habitat. However, as habitat modeling in Garrison 2007 demonstrates, the water temperature bathymetry correlates preferred by calving right whales degrade from the optimal values of these variables with increasing distance from shore. Mean right whale calving density as a function of distance from shore predicted by the model is nearly zero at 35 nm (64.82 km) from shore. Therefore, NMFS has determined that a 35–nm (64.82–km) boundary provides a sufficient buffer from the 27–nm (50–km) distance predicted by the habitat model. NMFS is therefore maintaining the 35–nm (64.82–km) management boundary for waters off South Carolina.

NMFS is not expanding the seaward boundary of the restricted area to the edge of the EEZ. This final rule is specific to right whale protection from gillnet fishing activity in critical calving area. While right whale survey effort is low east of 80° W. long., the Gulf Stream apparently serves as a thermal boundary to the eastward movements of right whales in the Southeast U.S. (Keller *et al.*, 2006).

Comment 13: NMFS received several comments regarding the proposed changes to the restricted period. Two commenters recommended that the restricted period for the Southeast U.S. Restricted Area North be extended to November 1 through April 30 instead of the current period of November 15 to March 31 to adequately protect right whale mothers and calves in the calving area. One of these commenters stated that migration patterns of right whales are not well known, and appropriate closure periods will be determined more reliably as more is learned; however, the whales must occur in the northern area both earlier and later in the season than in the southern area, for the southward and northward migration. Another commenter proposed alternate dates for the restricted period for the right whale critical habitat area. This commenter requested that April 1 remain the ending date for the restricted period. More specifically, the commenter asked that the area south of the Georgia/Florida border open for the whiting fishery on April 1, and the area between the North Carolina/South Carolina border and the Georgia/Florida border remain closed through April 15, on the basis that this would allow right whales to exit the area on their northward migration route, and allow fishermen to salvage a two week fishing season (during the first portion of April) while water temperatures are favorable for a viable fishery.

Response: The ALWTRP regulations at 50 CFR 229.32(g)(2)(v) authorize the AA to revise the restricted period if NMFS determines that right whales are remaining longer than expected in a closed area or have left earlier than expected. In developing this final rule, NMFS considered whether right whales were remaining longer in or leaving earlier from the Southeast U.S. Restricted Area than previously expected, recognizing that a substantial amount of aerial survey data and opportunistic sightings of right whales have been collected since the ALWTRP regulations were originally promulgated in 1997. The November 15 through March 31 timeframe was established as the restricted period for the entire Southeast U.S. Restricted Area in the original ALWTRP regulations. More recent data indicate that right whales are rarely sighted south of 29° N. lat. in November or in April; however, right whales have been sighted throughout the area north of 29° N. lat. and extending north to the South Carolina/North Carolina border from mid-November through mid-April. Consequently, in accordance with 50 CFR 229.32(g)(2)(v), NMFS has determined that it is appropriate to modify the annual restricted period to include two restricted periods specific to the northern and southern zones of the Southeast U.S. Restricted Area: November 15 through April 15 north of 29° N. lat. and December 1 through March 31 south of 29° N. lat. This is consistent with NMFS' June 21, 2005, proposed rule to amend the ALWTRP(70 FR 35894). NMFS believes the dates are sufficiently protective of right whale mothers and calves during their southward and northward migration.

NMFS specifically re-evaluated available information in consideration of the alternate restricted period proposed by one commenter and described above, for the area south of the Georgia/Florida border. This information included habitat models and right whale sightings data from aerial surveys geographically stratified as north and south of the Georgia/Florida border. Habitat models predict right whales to be present south of the Georgia/Florida state boundary and as far south as Cape Canaveral through the end of March (Garrison 2007), indicating that whales would be migrating through the Southeast U.S. Restricted Area North during the first two weeks of April. This is confirmed by right whale sighting data from aerial surveys. NMFS reviewed effort-corrected right whale sighting records contained in the University of Rhode Island database for the area between 29° N. lat. and the Georgia/Florida border (30° 42.5′ N. lat.) for right whale sightings from April 1 to April 15. The mean number of sightings per unit of survey effort is zero for the area south of the Georgia/Florida border in the second half of April, but greater than zero during the first half of April, indicating that right whales are present in that area through mid-April. NMFS believes that allowing gillnet fishing in the area south of the Georgia/Florida border annually after March 31 would pose an unacceptable risk to right whales.

Comment 14: Comments were received requesting additional exemptions to the prohibition on gillnet fishing and possession during the restricted period. These exemptions include beach-based recreational gillnetting in South Carolina, scientific research using gillnets, and traversing through Little River Inlet with fish on board. One commenter stated that any additional exemptions should be minimized and granted only in areas where such activities will not take right whales. Others opposed any additional exemptions. Finally, some commenters not only opposed additional exemptions but supported increased restrictions of gillnets and other fishing gear types.

Response: NMFS reiterates that this final rule implements and amends the

ALWTRP regulations under the MMPA and the ESA and applies only to certain commercial fisheries that interact with large whales. This final rule does not apply to recreational fishing or non-commercial fishing for scientific research if no sale or barter is involved. While NMFS has the statutory authority to issue protective regulations for right whale impacts caused by activities other than commercial fisheries, that is beyond the scope of this action which was triggered by existing regulatory requirements in 50 CFR 229.32(g)(1).

Recreational and research gillnetting are not exempt from the take prohibitions under either the ESA or MMPA, and would need applicable authorizations if right whale takes were anticipated. South Carolina Department of Natural Resources permits a licensed recreational surf gillnet fishery that currently includes 212 participants operating mainly along the state's northern coast, and states they believe the characteristics of the fishery make the likelihood of interaction with large whales extremely low. Nets are restricted to no longer than 100 feet (30.48 m) and are used in unrestricted areas of the Atlantic Ocean, typically in water depths less than 8 feet (2.44 m). Fishermen are required to remain within 500 feet (152.4 m) or ''hailing distance'' of their nets at all times. Given the bathymetry off South Carolina's Atlantic beaches, gillnet gear is unlikely to extend into depths where right whales would normally occur.

NMFS continually works with state fishery management agencies in the southeast U.S. to develop conditions for research permits for the safe conduct of research activities that avoid potential impacts to right whales. These conditions may include limits on net length, number of nets, soak time, tending requirements, observer requirements, disentanglement training, breakaway panels, and endline modifications. To date, fishing effort has been very low for scientific research gillnetting.

NMFS agrees that it is reasonable to allow gillnet vessels to transit in and out of the Little River Inlet and is modifying the restricted area accordingly in this final rule. NMFS has moved the boundary of the restricted area southward to exclude the Little River Inlet from the Southeast U.S. Restricted Area. This modification will allow fishermen who participate in a legal commercial gillnet fishery off the southeastern coast of North Carolina to transit through Little River Inlet on the South Carolina/North Carolina border with gillnets and fish onboard. This measure alleviates safety concerns associated with fishermen in small vessels (typically less than 24 feet (7.3 m)) being required to use the closest navigable inlet beyond the restricted area, Shallotte Inlet, which is approximately 10 nm (18.52 km) away and can become unsafe in certain weather conditions. The modification poses no additional risk to right whales because the change in area is very small and gillnetting will remain prohibited in South Carolina state waters surrounding the inlet.

Comment 15: Several commenters stated they support the gillnet closure in the Southeast U.S., but believe that additional measures should be taken to protect right whales in other areas, including the North Pacific Ocean, Stellwagen Bank National Marine Sanctuary, other National Marine Sanctuaries, and Cape Cod Bay. Comments were also received requesting protections for right whales in areas outside of U.S. jurisdiction.

Response: The purpose of this final rule is to implement existing ALWTRP regulations at 50 CFR 229.32(g)(1) and (2), with associated revisions to 50 CFR 229.32(f), in response to the January 22, 2006, right whale calf mortality. The regulations only cover the Southeast U.S. calving area; therefore, measures addressing other geographical areas are outside the scope of this rulemaking.

Summary of Changes in This Final Rule Relative to the Proposed Rule

Based on comments received, NMFS has changed the final rule from the proposed rule to exclude the Little River entrance, South Carolina, from the expanded Southeast U.S. Restricted Area. Coordinates contained in the table in 50 CFR 229.32(f)(1)(i) have been revised to reflect this change. Figure 1 illustrates the Southeast U.S. Restricted Area as modified by this final rule. Furthermore, paragraph 229.32(f)(3) that addresses observer requirements in the Southeast U.S. Observer Area, is modified to eliminate references to observer requirements for the Southeast U.S. Restricted Area North. Since this final rule eliminates gillnetting in the Southeast U.S. Restricted Area North, modifying this paragraph as specified will avoid confusion.

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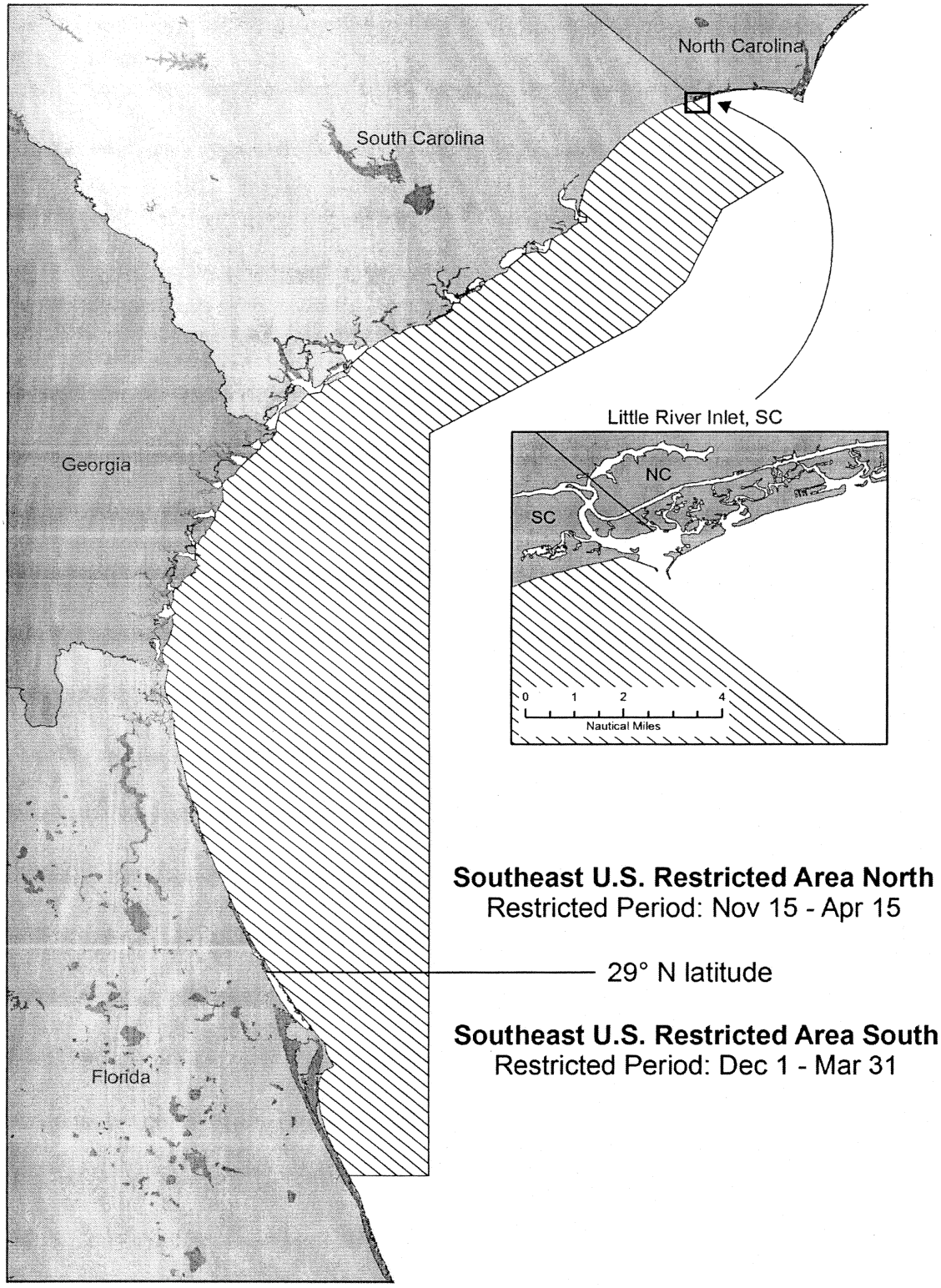

Figure 1. Revised Southeast U.S. Restricted Areas and Restricted Periods.

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Classification

In accordance with section 118(f)(9) of the MMPA, NMFS has determined that this action is necessary to implement take reduction measures to protect northern right whales in the North Atlantic. In addition, pursuant to section 11(f) of the ESA, NMFS is promulgating these regulations to enforce the ESA's prohibitions on the taking of endangered right whales.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

NMFS prepared an EA for this action, and the AA concluded that there will be no significant impact on the human environment as a result of this final rule. A copy of the EA is available from NMFS (see **ADDRESSES**).

A final regulatory flexibility analysis (FRFA) incorporates the IRFA, a summary of the significant issues raised by the public comments in response to the IRFA, and NMFS responses to those comments, and a summary of the analyses completed to support the action. A summary of the analysis follows. A copy of this analysis is available from NMFS (see **ADDRESSES**).

In summary, the purpose for this final rule is to implement the requirements of § 229.32(g)(1) and to reduce serious injury and mortality to northern right whales in the North Atlantic incidental to commercial gillnet fishing in the Southeast U.S. Atlantic Ocean, in response to the death of a right whale calf in January 2006. The implemented ALWTRP provisions as amended include expanding the Southeast U.S. Restricted Area and prohibiting gillnet fishing and possession within that area, with certain exemptions. The MMPA and the ESA provide the statutory bases for this final rule.

Commercial fishing vessels that operate in the expanded Southeast U.S. Restricted Area from November 15 through April 15 (waters off South Carolina, Georgia, and northeast Florida) and use gillnets are expected to be affected by this final rule. This final rule is expected to have greatest impact on gillnet fishermen targeting whiting, shark, and Spanish mackerel. Six to eight shark gillnet fishing vessels and up to 56 finfish gillnet fishing vessels are expected to be affected by this final rule. The Small Business Administration defines a small entity in the commercial fishing sector as a firm that is independently owned and operated, is not dominant in its field of operation, and has average annual gross receipts not in excess of $4 million (2002 NAICS 114111). It is assumed that all of the affected vessels represent small businesses. All of the vessels that are engaged in shark and finfish gillnet fishing in the expanded Southeast U.S. Restricted Area are small businesses. This final rule is expected to affect all of those businesses. Consequently, it is expected to affect a substantial number of small businesses.

Two comments were received pertaining to the IRFA or economic impacts specific to small entities resulting from the management actions presented in the proposed rule. A more expanded response to these comments is found above in the ''Comments on the Notice of Proposed Rulemaking and Responses'' section.

One commenter stated that the proposed regulations would disproportionately impact NC gillnetters targeting whiting, and stated that while other commercial fisheries have received limited exemptions, NC gillnet fishermen have no safe, viable economic alternative to continue fishing for whiting in the region. The Initial Regulatory Flexibility Analysis (IRFA) that NMFS prepared for the proposed rule analyzes the impacts to these fishermen. Based on this analysis, NMFS agrees that this final rule is expected to most greatly affect fishermen that fish for whiting in the Southeast U.S. Restricted Area North. NMFS notes, however, that all gillnet fishing will be prohibited by this final rule in the Southeast U.S. Restricted Area North, not just whiting fishing. In addition, comments made by whiting fishermen at the SE Subgroup meeting suggest these losses could be mitigated by moving into other areas, or targeting other species at other times of the year, or both, resulting in minimal long-term impacts for these fishermen from the final rule. Finally, at the SE Subgroup meeting, NMFS inquired about the feasibility of fishing for whiting in other areas, such as the Southeast U.S. Restricted Area South, but fishermen reported that a unique habitat feature off northeast Florida resulted in a very localized concentration of whiting and this is where whiting gillnet fishing effort was necessarily focused. No changes were made to this final rule relative to this comment.

Several commenters expressed concern regarding safety and fuel costs for fishermen that work out of Little River Inlet and fish off North Carolina. NMFS has removed this burden by moving the boundary of the restricted area southward to exclude the Little River Inlet from the Southeast U.S. Restricted Area. As discussed in the preamble of this final rule, NMFS has modified the expanded Southeast U.S. Restricted Area to exclude the Little

River Inlet. The estimated economic impacts in the IRFA are not expected to change, as affecting legal gillnet fishing off North Carolina was an unintentional and unknown effect of the proposed rule.

This final rule prohibits gillnet fishing in the northern zone of the expanded restricted area, during the restricted period, without exemptions. This final action is expected to reduce average annual shark gillnet revenue in the northern zone by $4,029. Total shark gillnet landings in Florida north of 29° N. lat. from November 1 through April 30 varied from zero to 38,229 lbs (17,340 kg) during the years from 2000 through 2004, with an annual average of 12,768 lbs (5,804 kg) and a dockside value of $7,712. These averages represent an over-estimation of losses from reduced shark gillnet landings in Florida from the northern zone because the restricted period is actually from November 15 through April 15, not November 1 through April 30. If November landings during the restricted period represent 50 percent of all November landings, and if April landings during the restricted period represent 50 percent of all April landings, this final rule is expected to reduce total shark gillnet landings in Florida from the northern zone by $3,856 and 6,384 lbs (2,902 kg). This final rule is expected to reduce average annual shark gillnet landings by 6,636 lbs (3,016 kg) and average annual shark gillnet revenue in the northern zone (South Carolina and Florida combined) by $4,029 ($3,856 from Florida plus $173 from South Carolina), assuming not all November and April landings occur in the restricted period.

This final rule prohibits gillnet fishing during the restricted period in a southern zone of the expanded restricted area with certain limited exemptions for shark and Spanish mackerel gillnet fishing. The southern zone is composed of Trip Ticket area 732, which lies entirely in waters off Florida. This final rule is expected to have no effect on shark gillnet revenues in the southern zone because current shark gillnet requirements in the southern zone are the same as the requirements for the exemptions in this final action.

The average annual shark gillnet revenue expected to be lost as a result of this final rule is $4,029 ($4,029 from the northern zone plus $0 from the southern zone), which represents about 2 percent of annual shark gillnet revenues from the combined zones. As six to eight shark gillnet fishing vessels are expected to be affected by this final rule, each shark gillnet fishing vessel is expected to lose on average from $504 to $672 annually from lost shark landings.

It is estimated that Spanish mackerel gillnet fishermen in the northern zone may lose on average 1,509 lbs (686 kg) of Spanish mackerel with an average dockside value of $1,159 annually. During the 6–month period from November 1 through April 30 from 2000 through 2004, an average of 102 lbs (46 kg) of Spanish mackerel with a dockside value of $86 were landed from gillnets and caught in the northern zone. In the first four months of 2005, however, 1,509 lbs (686 kg) with a dockside value of $1,159 were landed from gillnets. It is possible that, since 2005, Spanish mackerel fishers are increasingly targeting the species in the northern zone during these 5 months. Consequently, November through December 2004 and January through April 2005 landings of Spanish mackerel were used to estimate losses of gillnet landings to Spanish mackerel fishers in the northern zone, although this method may significantly over-estimate losses to Spanish mackerel gillnet fishers who operate in the northern zone. These northern zone landings represent less than half a percent of annual Spanish mackerel landings in the Southeast U.S. Restricted Area.

Annual losses to Spanish mackerel gillnet fishers in the southern zone are expected to be $2,928 on average. Spanish mackerel gillnet fishers will not be able to take the species in the southern zone during the months of January and February. From 2000 through 2004, landings during these 2 months averaged 5,442 lbs (2,474 kg), with a dockside value of $2,928, annually. This analysis assumes Spanish mackerel gillnet fishers will not experience any losses of landings during the other months of the restricted period because exemptions to this final rule are consistent with existing Spanish mackerel gillnet operations during these other months. Consequently, annual losses to Spanish mackerel gillnet fishers in the southern zone are expected to be $2,928 (5,442 lbs; 2,474 kg). These southern zone landings represent about 1.5 percent of annual Spanish mackerel gillnet landings in the Southeast U.S. Restricted Area.

The combined loss of landings from the northern and southern zones of Spanish mackerel are expected to be 6,951 lbs (3,160 kg; $4,087). This combined loss represents approximately 2 percent of pounds annually landed in the Southeast U.S. Restricted Area.

Average annual losses of king whiting from the northern zone are expected to be 356,604 lbs (162,093 kg) with a dockside value of $276,824. Average annual landings of king whiting during the 5–month period between November through April from 2000 through 2004 vary significantly from landings during the first 4 months of 2005. Consequently, November and December 2004 figures and the January through April 2005 figures are used to estimate average annual losses of gillnet landings of king whiting from the northern zone. If all November and April landings occur within the restricted period, average annual losses of king whiting landings in the northern zone are expected to be 419,418 lbs (190,245 kg) with a value of $327,053. However, if November and April landings are evenly distributed throughout those months, estimated loss of landings during the restricted period are expected to represent 50 percent of November and April landings, respectively (since the restricted period begins November 15 and ends April 15), average annual losses of king whiting from the northern zone are expected to be 356,604 lbs (162,093 kg) with a dockside value of $276,824.

Average annual losses of king whiting landings from the southern zone are expected to be 4,255 lbs (1,934 kg) with a dockside value of $4,318. During the above 4–month period from 2000 through 2004, an average of 4,255 lbs (1,934 kg) of king whiting were landed in the southern zone with a dockside value of $4,318, annually. Figures from January 1 through March 31, 2005, do not suggest that king whiting gillnet fishers are increasingly targeting the species in the southern zone.

The combined loss of king whiting landings from the northern and southern zones are expected to be 360,859 lbs (164,027 kg; $281,142). The combined loss represents at least 70 percent of pounds landed annually in the Southeast U.S. Restricted Area.

Three other alternative operational measures were considered in this rulemaking. Alternative 1, a no-action alternative, was rejected because it would not address the risk of serious injury or mortality posed by commercial gillnet fishing to right whales in their calving area evidenced by the 2006 death of a right whale calf.

Alternative 2 would implement permanent limited operational restrictions in the expanded Southeast U.S. Restricted Area during the current restricted period of November 15 through March 31, annually. Enacting operational restrictions, as detailed in section 2.2.2 of the EA, would provide a reduction in the likelihood of gillnet gear interactions with endangered right

whales, reducing the risk of serious injury and mortality. This alternative would also result in a reduction in the risk of injury or mortality to other species that may become incidentally entangled in gillnet gear. However, the restrictions would only reduce and not eliminate the threat of serious injury and mortality of right whales from interacting with gillnet gear.

Alternative 3 would implement the immediate closure of the expanded Southeast U.S. Restricted Area to all gillnets from November 15 through March 31 annually on a permanent basis. No exemptions would be provided during the closure. Losses of gillnet landings caused by Alternative 3 would be equal to losses of gillnet landings caused by Alternative 2 plus losses of king whiting gillnet landings. Alternative 2 would be expected to reduce gillnet dockside revenues by $84,506 ($16,944, $50,447, $642, $4,742, and $11,731 from reduced landings of shark, Spanish mackerel, King mackerel, Bluefish, and ''Other Species'', respectively). Average annual losses to king whiting fishers caused by Alternative 3 were expected to be 348,301 lbs (158,319 kg), with dockside revenues of $271,696. Combined, Alternative 3 would be expected to result in losses of dockside revenue of $356,202. This alternative had the greatest economic impact of all alternatives, and was therefore not selected.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. A small entity compliance guide was prepared as part of this rulemaking process. The guide will be sent to all registered gillnet fishers in the Marine Mammal Authorization Program in South Atlantic states. Guides will also be provided to state resource management agencies, the USCG, and others as appropriate for distribution to the fishing industry. In addition, copies of this final rule and guide are available from NMFS and on the ALWTRP website (see **ADDRESSES**).

This final rule does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act (PRA). Any information collection requirements subject to PRA and related to VMS or observer requirements were addressed in previous rulemakings.

This final rule does not duplicate, overlap, or conflict with other Federal rules. NMFS is presently finalizing a proposed rule that addresses broad modifications to the ALWTRP (70 FR 35894). When finalized, that rule will incorporate modifications to the ALWTRP that result from this final rule on gillnet fishing in the Southeast U.S.

List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

Dated: June 19, 2007.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

■ For reasons set out in the preamble, 50 CFR part 229 is amended as follows:

PART 229—AUTHORIZATION FOR COMMERCIAL FISHERIES UNDER THE MARINE MAMMAL PROTECTION ACT OF 1972

■ 1. The authority citation for part 229 is revised to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*; § 229.32(f) also issued under 16 U.S.C. 1531 *et seq.*

■ 2. In § 229.2, the definitions of ''*Shark gillnetting,*'' ''*Strikenet or to fish with strikenet gear,*'' and ''*To strikenet for sharks*'' are removed.

■ 3. In § 229.32, paragraphs (f)(1)(i), (f)(3), (f)(4), and (g)(1) are revised to read as follows:

§ 229.32 Atlantic large whale take reduction plan regulations.

* * * * *

(f) * * *

(1) * * *

(i) *Southeast U.S. Restricted Area.* The Southeast U.S. Restricted Area consists of the area bounded by straight lines connecting the following points in the order stated from south to north, unless the Assistant Administrator changes that area in accordance with paragraph (g) of this section:

Point	N. Lat.	W. Long.
SERA1	27°51′	(1)
SERA2	27°51′	80°00′
SERA3	32°00′	80°00′
SERA4	32°36′	78°52′
SERA5	32°51′	78°36′
SERA6	33°15′	78°24′
SERA7	33°27′	78°04′
SERA8	(2)	78°33.9′

[1]Florida shoreline.

[2]South Carolina shoreline.

(A) *Southeast U.S. Restricted Area N.* The Southeast U.S. Restricted Area N consists of the Southeast U.S. Restricted Area from 29°00′ N. lat. northward.

(B) *Southeast U.S. Restricted Area S.* The Southeast U.S. Restricted Area S consists of the Southeast U.S. Restricted Area southward of 29°00′ N. lat.

* * * * *

(3) *Observer requirement.* No person may fish for shark with gillnet with webbing of 5 inches (12.7 cm) or greater stretched mesh in the southeast U.S. observer area from December 1 through March 31 south of 29°00′ N. lat. unless the operator of the vessel calls the Southeast Fisheries Science Center Panama City Laboratory in Panama City, FL, not less than 48 hours prior to departing on any fishing trip in order to arrange for observer coverage. If the Panama City Laboratory requests that an observer be taken on board a vessel during a fishing trip at any time from December 1 through March 31 south of 29°00′ N. lat., no person may fish with such gillnet aboard that vessel in the southeast U.S. observer area unless an observer is on board that vessel during the trip.

(4) *Restricted periods, closure, and exemptions.*

(i) *Restricted periods.* The restricted period for the Southeast U.S. Restricted Area N is from November 15 through April 15, and the restricted period for the Southeast U.S. Restricted Area S is from December 1 through March 31, unless the Assistant Administrator revises the restricted period in accordance with paragraph (g) of this section.

(ii) *Closure for gillnets.*

(A) Except as provided under paragraph (f)(4)(v) of this section, fishing with or possessing gillnet in the Southeast U.S. Restricted Area N during the restricted period is prohibited.

(B) Except as provided under paragraph (f)(4)(iii) of this section and (f)(4)(iv) of this section, fishing with gillnet in the Southeast U.S. Restricted Area S during the restricted period is prohibited.

(iii) *Exemption for Southeastern U.S. Atlantic shark gillnet fishery.* Fishing with gillnet for sharks with webbing of 5 inches (12.7 cm) or greater stretched mesh is exempt from the restrictions under paragraph (f)(4)(ii)(B) if:

(A) The gillnet is deployed so that it encloses an area of water;

(B) A valid commercial directed shark limited access permit has been issued to the vessel in accordance with 50 CFR § 635.4(e) and is on board;

(C) No net is set at night or when visibility is less than 500 yards (1,500 ft, 460 m);

(D) The gillnet is removed from the water before night or immediately if visibility decreases below 500 yards (1,500 ft, 460 m);

(E) Each set is made under the observation of a spotter plane;

(F) No gillnet is set within 3 nautical miles (5.6 km) of a right, humpback, or fin whale; and

(G) The gillnet is removed immediately from the water if a right, humpback, or fin whale moves within 3 nautical miles (5.6 km) of the set gear.

(iv) *Exemption for Spanish Mackerel component of Southeast Atlantic gillnet fishery.* Fishing with gillnet for Spanish mackerel is exempt from the restrictions under paragraph (f)(4)(ii)(B) from December 1 through December 31, and from March 1 through March 31 if:

(A) Gillnet mesh size is between 3.5 inches (8.9 cm) and 4 7/8 inches (12.4 cm) stretched mesh;

(B) A valid commercial vessel permit for Spanish mackerel has been issued to the vessel in accordance with 50 CFR § 622.4(a)(2)(iv) and is on board;

(C) No person may fish with, set, place in the water, or have on board a vessel a gillnet with a float line longer than 800 yards(2,400 ft, 732 m);

(D) No person may fish with, set, or place in the water more than one gillnet at any time;

(E) No more than two gillnets, including any net in use, may be possessed at any one time; provided, however, that if two gillnets, including any net in use, are possessed at any one time, they must have stretched mesh sizes (as allowed under the regulations) that differ by at least .25 inch (.64 cm);

(F) No person may soak a gillnet for more than 1 hour. The soak period begins when the first mesh is placed in the water and ends either when the first mesh is retrieved back on board the vessel or the gathering of the gillnet is begun to facilitate retrieval on board the vessel, whichever occurs first; providing that, once the first mesh is retrieved or the gathering is begun, the retrieval is continuous until the gillnet is completely removed from the water;

(G) No net is set at night or when visibility is less than 500 yards (1,500 ft, 460 m);

(H) The gillnet is removed from the water before night or immediately if visibility decreases below 500 yards (1,500 ft, 460 m);

(I) No net is set within 3 nautical miles (5.6 km) of a right, humpback, or fin whale; and

(J) Gillnet is removed immediately from the water if a right, humpback, or fin whale moves within 3 nautical miles (5.6 km) of the set gear.

(v) *Exemption for vessels in transit with gillnet aboard.* Possession of gillnet aboard a vessel in transit is exempt from the restrictions under paragraph (f)(4)(ii)(A) of this section if: All nets are covered with canvas or other similar material and lashed or otherwise securely fastened to the deck, rail, or drum; and all buoys, high flyers, and anchors are disconnected from all gillnets. No fish may be possessed aboard such a vessel in transit.

(g) * * *

(1) *Entanglements in critical habitat or restricted areas.* If a serious injury or mortality of a right whale occurs in the Cape Cod Bay critical habitat from January 1 through May 15, the Great South Channel Restricted Area from April 1 through June 30, the Southeast U.S. Restricted Area N from November 15 through April 15, or the Southeast U.S. Restricted Area S from December 1 through March 31 as the result of an entanglement by lobster or gillnet gear allowed to be used in those areas and times, the Assistant Administrator shall close that area to that gear type (i.e., lobster trap or gillnet) for the rest of that time period and for that same time period in each subsequent year, unless the Assistant Administrator revises the restricted period in accordance with paragraph (g)(2) of this section or unless other measures are implemented under paragraph (g)(2) of this section.

* * * * *

[FR Doc. E7–12251 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 72, No. 121
Monday, June 25, 2007

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE270; Notice No. 23–07–02–SC]

Special Conditions: Adam Aircraft, Model A700; Fire Extinguishing for Aft Fuselage Mounted Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Adam Aircraft, Model A700 airplane. This airplane will have a novel or unusual design feature(s) associated with aft mounted engine fire protection. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: We must receive your comments by July 25, 2007.

ADDRESSES: Mail two copies of your comments to: Federal Aviation Administration, Regional Counsel, ACE–7, 901 Locust, Room 506, Kansas City, Missouri 64106. You may deliver two copies to the Small Airplane Directorate at the above address. Mark your comments: Docket No. CE270. You may inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Leslie B. Taylor, Regulations & Policy Branch, ACE–111, Federal Aviation Administration, Small Airplane Directorate, Aircraft Certification Service, 901 Locust, Kansas City, MO 64106; telephone (816) 329–4134; facsimile (816) 329–4090, e-mail at *leslie.b.taylor@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite interested parties to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning these special conditions. You may inspect the docket before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

If you want the FAA to acknowledge receipt of your comments on this proposal, include with your comments a pre-addressed, stamped postcard on which the docket number appears. We will stamp the date on the postcard and mail it back to you.

Background

On April 12, 2004, Adam Aircraft applied for a type certificate for their new Model A700. The Model A700, is a 6 to 8 seat, pressurized, retractable-gear, composite structure airplane with two turbofan engines mounted on pylons on either side of the aft fuselage.

Part 23 has historically addressed fire protection through prevention, identification, and containment. Prevention has been provided through minimizing the potential for ignition of flammable fluids and vapors. Identification has been provided by locating engines within the pilots' primary field of view and/or with the incorporation of fire detection systems. This has provided both rapid detection of a fire and confirmation when it was extinguished. Containment has been provided through the isolation of designated fire zones, through flammable fluid shutoff valves, and firewalls. This containment philosophy also ensures that components of the engine control system will function effectively to permit a safe shutdown of an engine. However, containment has only been demonstrated for 15 minutes. If a fire occurs in traditional part 23 airplanes, the appropriate corrective action is to land as soon as possible. For a small, simple airplane originally envisioned by part 23, it is possible to descend and land within 15 minutes. Thus, the occupants can safely exit the airplane before the firewall is breached. These simple airplanes normally have the engine located away from critical flight control systems and primary structure. This has ensured that, throughout a fire event, a pilot can continue safe flight, and it has made the prediction of fire effects relatively easy. Other design features of these simple aircraft, such as low stall speeds and short landing distances, ensure that even in the event of an off field landing, the potential for the outcome being catastrophic has been minimized.

Title 14 CFR, part 23, did not envision the type of configuration of the Model A700 airplane. The Model A700 incorporates two turbofan engines located on pylons on either side of the aft fuselage. These engines are not in the pilots' field of view. With the location in the aft fuselage, the ability to visually detect a fire is minimal.

Type Certification Basis

Under 14 CFR 21.17, Adam Aircraft must show that the Model A700 meets the applicable provisions of part 23, as amended by Amendments 23–1 through 23–55 thereto.

If the Administrator finds that the applicable airworthiness regulations in 14 CFR part 23 do not contain adequate or appropriate safety standards for the Model A700 because of a novel or unusual design feature, special conditions are prescribed under § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model A700 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in § 11.19, under § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

Novel or Unusual Design Features

The Model A700 will incorporate the following novel or unusual design features:

The Model A700 incorporates two turbofan engines located on pylons on either side of the aft fuselage. These engines are not in the pilots' field of view. The effects of a fire in such a compartment are more varied and adverse than the typical engine fire in a simple part 23 airplane. With the location in the aft fuselage, the ability to visually detect a fire is minimal. However, the ability to extinguish an engine fire becomes extremely critical with the Model A700 engine location.

While the certification basis for the Model A700 requires that a fire detection system be installed due to the engine location, fire extinguishing is also considered a requirement. A sustained fire could result in loss of control of the airplane and damage to primary structure before an emergency landing could be made. Because of the location of critical structures and flight controls, a means to minimize the probability of re-ignition from occurring is necessary. One acceptable method to minimize re-ignition is to install a two-shot system. The effects of a fire emanating from an enclosed engine installation are more varied, adverse, and more difficult to predict than an engine fire envisioned for typical part 23 airplanes.

Discussion

The engines are on pylons on either side of the aft fuselage so there is a need to prevent flammable vapors, flammable fluids, and flame from accumulating. Finally, there is a need to extinguish fires.

Applicability

As discussed above, these special conditions are applicable to the Model A700. Should Adam Aircraft apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, and 44701; 14 CFR 21.16 and 21.17; and 14 CFR 11.38 and 11.19.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Adam Aircraft, Model A700 airplanes.

Aft fuselage mounted engines need to protect the airplane from fires that were not envisioned in the development of part 23. Therefore, special conditions for a fire extinguishing system are required for airplanes with this engine configuration.

Regulations requiring and defining engine compartment fire extinguishing systems already exist for part 23 commuter category airplanes. These regulations will provide an adequate level of safety for the normal category Model A700 aircraft with its aft pylon mounted engines.

As the extinguishing agent is subject to change during the service life of the airplane, the certification basis has the need to include 14 CFR part 23, § 23.1197 in its entirety.

Each fire zone should be ventilated to prevent the accumulation of flammable vapors. It must also be designed such that it will not allow entry of flammable fluids, vapors, or flames from other fire zones. It must be designed such that it does not create an additional fire hazard from the discharge of vapors or fluids.

1. SC 23.1195—Add the requirements of § 23.1195 while deleting ''For commuter category airplanes.''

23.1195, Fire Extinguishing Systems

(a) Fire extinguishing systems must be installed and compliance shown with the following:

(1) Except for combustor, turbine, and tailpipe sections of turbine-engine installations that contain lines or components carrying flammable fluids or gases for which a fire originating in these sections is shown to be controllable, a fire extinguisher system must serve each engine compartment;

(2) The fire extinguishing system, the quantity of extinguishing agent, the rate of discharge, and the discharge distribution must be adequate to extinguish fires. An individual ''one-shot'' system may be used except for embedded engines where a ''two-shot'' system is required.

(3) The fire extinguishing system for a nacelle must be able to simultaneously protect each compartment of the nacelle for which protection is provided.

(b) If an auxiliary power unit is installed in any airplane certificated to this part, that auxiliary power unit compartment must be served by a fire extinguishing system meeting the requirements of paragraph (a)(2) of this section.

2. SC 23.1197—Add the requirements of § 23.1197 while deleting ''For commuter category airplanes.''

23.1197, Fire Extinguishing Agents

The following applies:

(a) Fire extinguishing agents must—

(1) Be capable of extinguishing flames emanating from any burning fluids or other combustible materials in the area protected by the fire extinguishing system; and

(2) Have thermal stability over the temperature range likely to be experienced in the compartment in which they are stored.

(b) If any toxic extinguishing agent is used, provisions must be made to prevent harmful concentrations of fluid or fluid vapors (from leakage during normal operation of the airplane or as a result of discharging the fire extinguisher on the ground or in flight) from entering any personnel compartment, even though a defect may exist in the extinguishing system. This must be shown by test except for built-in carbon dioxide fuselage compartment fire extinguishing systems for which—

(1) Five pounds or less of carbon dioxide will be discharged under established fire control procedures into any fuselage compartment; or

(2) Protective breathing equipment is available for each flight crewmember on flight deck duty.

3. SC 23.1199—Add the requirements of § 23.1199 while deleting ''For commuter category airplanes.''

23.1199, Extinguishing Agent Containers

The following applies:

(a) Each extinguishing agent container must have a pressure relief to prevent bursting of the container by excessive internal pressures.

(b) The discharge end of each discharge line from a pressure relief connection must be located so that discharge of the fire-extinguishing agent would not damage the airplane. The line must also be located or protected to

prevent clogging caused by ice or other foreign matter.

(c) A means must be provided for each fire extinguishing agent container to indicate that the container has discharged or that the charging pressure is below the established minimum necessary for proper functioning.

(d) The temperature of each container must be maintained, under intended operating conditions, to prevent the pressure in the container from—

(1) Falling below that necessary to provide an adequate rate of discharge; or

(2) Rising high enough to cause premature discharge.

(e) If a pyrotechnic capsule is used to discharge the fire extinguishing agent, each container must be installed so that temperature conditions will not cause hazardous deterioration of the pyrotechnic capsule.

4. SC 23.1201—Add the requirements of § 23.1201 while deleting ''For commuter category airplanes.''

23.1201, Fire Extinguishing System Materials

The following apply:

(a) No material in any fire extinguishing system may react chemically with any extinguishing agent so as to create a hazard.

(b) Each system component in an engine compartment must be fireproof.

Issued in Kansas City, Missouri, on June 14, 2007.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–12121 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28378; Directorate Identifier 2007–NM–089–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 727 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Boeing Model 727 airplanes. This proposed AD would require doing an initial detailed inspection for cracks in the aft pressure bulkhead web; repairing any discrepancy; and doing repetitive detailed inspections, and doing related investigative actions, if necessary. This proposed AD results from reports of cracking in the aft pressure bulkhead web. We are proposing this AD to detect and correct a cracked pressure bulkhead web, which could result in rapid decompression of the airplane.

DATES: We must receive comments on this proposed AD by August 9, 2007.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Room W12–140 on the ground floor of the West Building, 1200 New Jersey, Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for the service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6577; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any relevant written data, views, or arguments regarding this proposed AD. Send your comments to an address listed in the **ADDRESSES** section. Include the docket number ''FAA–2007–28378; Directorate Identifier 2007–NM–089–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

Examining the Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Operations office (telephone (800) 647–5527) is located on the ground level of the West Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Discussion

We have received a report of a 6.8-inch crack oriented horizontally in the aft pressure bulkhead web located at station 1183 at water line 210 from right buttock line (RBL) 50.7 to RBL 57.5. We also have received a report of a 14.5-inch crack in the same bay between left buttock line (LBL) 46 to LBL 63. These events occurred on Boeing Model 727 airplanes. The cracks were attributed to fatigue of the pressure bulkhead web due to cabin pressurization cycles. Analysis by Boeing revealed multiple crack origins along the length of the web, which propagated through the web thickness. A cracked pressure bulkhead web, if not corrected, could result in rapid decompression of the airplane.

Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletin 727–53–0230, dated January 8, 2007. The service information describes the following procedures:

- Doing an initial detailed inspection for cracks in the aft pressure bulkhead web;
- Doing repetitive detailed inspections if necessary; and
- Repairing any crack, doing related investigative actions if necessary, and contacting Boeing for certain repairs. The related investigative actions include a high frequency eddy current inspection and a detailed inspection to make sure that structure common to the

repair installation is crack free and that no disbonding or corrosion is present.

The compliance time for the initial detailed inspection is before the accumulation of 40,000 total flight cycles, or within 3,500 flight cycles after the date of the service bulletin, whichever occurs later. The repeat interval is 12,000 flight cycles.

Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. For this reason, we are proposing this AD, which would require accomplishing the actions specified in the service information described previously, except as discussed under ''Differences Between the Proposed AD and the Service Information.''

Differences Between the Proposed AD and the Service Information

The service information specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- Using a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization whom we have authorized to make those findings.

Costs of Compliance

There are about 842 airplanes of the affected design in the worldwide fleet. This proposed AD would affect about 459 airplanes of U.S. registry. The proposed detailed inspection would take about 1 work hour per airplane, at an average labor rate of $80 per work hour. Based on these figures, the estimated cost of the proposed AD for U.S. operators is $36,720, or $80 per airplane.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

Boeing: Docket No. FAA–2007–28378; Directorate Identifier 2007–NM–089–AD.

Comments Due Date

(a) The FAA must receive comments on this AD action by August 9, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from reports of cracking in the aft pressure bulkhead web. We are issuing this AD to detect and correct a cracked pressure bulkhead web, which could result in rapid decompression of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection(s) and Corrective Actions

(f) Do an initial detailed inspection for cracks in the aft pressure bulkhead web in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 727–53–0230, dated January 8, 2007; except as provided by note (a) in Table 1 of paragraph 1.E., ''Compliance,'' of the service bulletin. Do the inspection at the compliance time identified in paragraph 1.E., ''Compliance,'' of the service bulletin; except as provided by paragraph (g) of this AD.

(1) If no crack is found, repeat the detailed inspection at the repeat interval identified in paragraph 1.E., ''Compliance,'' of the service bulletin, except as provided by note (a) in Table 1 of paragraph 1.E., ''Compliance,'' of the service bulletin.

(2) If any crack is found, before further flight, repair the crack and do the related investigative actions, in accordance with the Accomplishment Instructions of the service bulletin. If any crack, disbonding, or corrosion is found during related investigative actions, before further flight, repair the discrepancy using a method approved in accordance with the procedures specified in paragraph (h) of this AD.

(g) Where Boeing Special Attention Service Bulletin 727–53–0230, dated January 8, 2007, specifies a compliance time after the date of the service bulletin, this AD requires compliance within the specified compliance time after the effective date of this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Issued in Renton, Washington, on June 18, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–12220 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28377; Directorate Identifier 2007–NM–063–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 and ERJ 190 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Periodic operational check of the firewall hydraulic shutoff valves, made during routine maintenance, has revealed that the failure rate of that component is significantly higher than expected. Such a dormant failure, when combined with further possible failures, such as engine fire, may lead to an unacceptable reduction of safety margins.

The unsafe condition is failure of the firewall hydraulic shutoff valve, which, in combination with an engine fire, could result in loss of hydraulic pressure or spread of an engine fire beyond the firewall. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by July 25, 2007.

ADDRESSES: You may send comments by any of the following methods:

- *DOT Docket Web Site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Streamlined Issuance of AD

The FAA is implementing a new process for streamlining the issuance of ADs related to MCAI. This streamlined process will allow us to adopt MCAI safety requirements in a more efficient manner and will reduce safety risks to the public. This process continues to follow all FAA AD issuance processes to meet legal, economic, Administrative Procedure Act, and **Federal Register** requirements. We also continue to meet our technical decision-making responsibilities to identify and correct unsafe conditions on U.S.-certificated products.

This proposed AD references the MCAI and related service information that we considered in forming the engineering basis to correct the unsafe condition. The proposed AD contains text copied from the MCAI and for this reason might not follow our plain language principles.

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2007–28377; Directorate Identifier 2007–NM–063–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The Agência Nacional de Aviação Civil (ANAC), which is the aviation authority for Brazil, has issued Brazilian Airworthiness Directives 2007–02–01 and 2007–02–02, both effective February 27, 2007 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI state:

Periodic operational check of the firewall hydraulic shutoff valves, made during routine maintenance, has revealed that the failure rate of that component is significantly higher than expected. Such a dormant failure, when combined with further possible failures, such as engine fire, may lead to an unacceptable reduction of safety margins.

The unsafe condition is failure of the firewall hydraulic shutoff valve, which, in combination with an engine fire, could result in loss of hydraulic pressure or spread of an engine fire beyond the firewall. The MCAI requires repetitive operational checks of the firewall hydraulic shutoff valve, and if necessary, replacement of the valve. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

EMBRAER has issued Service Bulletins 170–29–0013 and 190–29–0008, both dated December 13, 2006. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of

Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 126 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $10,080, or $80 per product, per inspection cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Empresa Brasileira de Aeronautica S.A. (EMBRAER): Docket No. FAA–2007–28377; Directorate Identifier 2007–NM–063–AD.

Comments Due Date

(a) We must receive comments by July 25, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to EMBRAER Model ERJ 170–100 LR, –100 STD, –100 SE, –100 SU, –200 LR, –200 STD, and –200 SU airplanes; and Model ERJ 190–100 STD, –100 LR, and –100 IGW airplanes; equipped with firewall hydraulic shutoff valves part number (P/N) 975287–3.

Subject

(d) Hydraulic power.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Periodic operational check of the firewall hydraulic shutoff valves, made during routine maintenance, has revealed that the failure rate of that component is significantly higher than expected. Such a dormant failure, when combined with further possible failures, such as engine fire, may lead to an unacceptable reduction of safety margins.

The unsafe condition is failure of the firewall hydraulic shutoff valve, which, in combination with an engine fire, could result in loss of hydraulic pressure or spread of an engine fire beyond the firewall. The MCAI requires repetitive operational checks of the firewall hydraulic shutoff valve, and if necessary, replacement of the valve.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) Within the next 600 flight hours after the effective date of this AD, and thereafter at intervals that do not exceed 600 flight hours, perform an operational check in accordance with EMBRAER Service Bulletin 170–29–0013, dated December 13, 2006; or EMBRAER Service Bulletin 190–29–0008, dated December 13, 2006; as applicable; for proper operation of the firewall hydraulic shutoff valves P/N 975287–3. If the valve does not operate properly, before further flight, replace the faulty hydraulic shutoff valve with another one bearing the same P/N.

Note 1: For the purpose of this AD, an operational check is: ''A task to determine that an item is fulfilling its intended purpose. The check does not require quantitative tolerances. This is a failure finding task.''

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: No Differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, ANM–116, International Branch, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1175; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) Airworthy Product: For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated

agent). You are required to assure the product is airworthy before it is returned to service.

(3) Reporting Requirements: For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI Brazilian Airworthiness Directives 2007–02–01 and 2007–02–02, both effective February 27, 2007; and EMBRAER Service Bulletins 170–29–0013 and 190–29–0008, both dated December 13, 2006; for related information.

Issued in Renton, Washington, on June 18, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–12224 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–138707–06]

26 CFR Part 1

RIN 1545–BF90

Exclusions from Gross Income of Foreign Corporations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations and notice of public hearing.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations that modify final regulations issued under section 883(a) and (c) of the Internal Revenue Code (Code), relating to income derived by foreign corporations from the international operation of ships or aircraft. Those regulations revise § 1.883–3 of the final regulations, relating to the treatment of controlled foreign corporations, following the repeal of section 954(a)(4) and (f) (foreign base company shipping provisions) by section 415 of the American Jobs Creation Act of 2004. In addition, those regulations provide guidance for foreign corporations organized in countries that provide an exemption from taxation solely through an income tax convention, and amend certain provisions in the current section 883 regulations. The text of those regulations serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by September 24, 2007. Outlines of topics to be discussed at the public hearing scheduled for Wednesday, October 24, 2007, at 10 a.m. must be received by Monday, September 24, 2007.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–138707–06), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–138707–06), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–138707–06).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Patricia A. Bray, at (202) 622–3880; concerning submissions of comments and/or requests for a hearing, Kelly Banks, at (202) 622–0392 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), and pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–1667.

Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP Washington, DC 20224. Comments on the collection of information should be received by August 24, 2007.

Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The collections of information in this proposed regulation are in §§ 1.883–2(f), 1.883–3(c) and (d), and 1.883–4(e). This information is required to enable a foreign corporation to determine if it is eligible to exclude its income from the international operation of ships or aircraft from gross income on its U.S. Federal income tax return. This information will also enable the IRS to monitor compliance with the provisions of the proposed regulations with respect to the stock ownership requirements of § 1.883–1(c)(2), and to make a preliminary determination of whether the foreign corporation is eligible to claim such an exemption and is accurately reporting income.

The collections of information are mandatory. The likely respondents are foreign corporations engaged in the international operation of ships or aircraft that wish to claim an exemption from U.S. tax under section 883, and certain of their shareholders owning (directly or indirectly) a majority of the value of the shares of such corporations.

Estimated total annual reporting/recordkeeping burden on foreign corporations: 1200 hours.

The estimated annual burden per respondent varies from 0 minutes to 3 hours, depending on the circumstances of the foreign corporation, with an estimated average of one hour.

Estimated number of respondents: 1,200.

Estimated annual frequency of responses: Once.

Estimated total annual reporting burden on shareholders: 925 hours.

The estimated annual burden per respondent varies from 1 minute to one hour, depending on the circumstances of the shareholder or intermediary, with an estimated average of 30 minutes.

Estimated number of respondents: 1850.

Estimated annual frequency of shareholder or intermediary responses: Once every three years if no information changes and once a year if a change in ownership information occurs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books and records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background and Explanation of Provisions

Temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** amend 26 CFR part 1. Those regulations amend the income inclusion test in § 1.883–3 of the final regulations issued in TD 9087 (68 FR 51394). Those regulations also address a number of comments that have been received concerning other portions of the final section 883 regulations. The text of those regulations serves as the text of these regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. Therefore, a regulatory assessment is not required. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a significant number of U.S. small entities. This certification is based on the fact that these regulations apply solely to foreign corporations, and impose only a limited collection of information burden on shareholders of such corporations, which in some cases may include U.S. small entities. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations and how they can be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for October 24, 2007, beginning at 10 a.m. in the IRS Auditorium of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written or electronic comments by September 24, 2007 and an outline of the topics to be discussed and the time devoted to each topic (a signed original and eight (8) copies) by September 24, 2007. A period of 10 minutes will be allocated to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these proposed regulations is Patricia A. Bray of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Par. 2. Section 1.883–0 is amended by revising the entries for §§ 1.883–1(g)(3) and (h)(3), 1.883–2(e)(2), 1.883–3, and 1.883–5(d) and (e) to read as follows:

§ 1.883–0 Outline of major topics.

* * * * *

§ 1.883–1 Exclusion of income from the international operation of ships or aircraft.

* * * * *

(g) * * *

(3) [The text of the proposed entry for § 1.883–1(g)(3) is the same as the text of the entry for § 1.883–1T(g)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

(h) * * *

(3) * * *

(i) through (iv) [The text of the proposed entries for § 1.883–1(h)(3)(i) through (iv) is the same as the text of the entries for § 1.883–1T(h)(3)(i) through (iv) published elsewhere in this issue of the **Federal Register**].

* * * * *

§ 1.883–2 Treatment of publicly traded corporations.

* * * * *

(e) * * *

(2) [The text of the proposed entry for § 1.883–2(e)(2) is the same as the text of the entry for § 1.883–2T(e)(2) published elsewhere in this issue of the **Federal Register**].

* * * * *

§ 1.883–3 Treatment of controlled foreign corporations.

* * * * *

[The text of the proposed entry for § 1.883–3 is the same as the entry for § 1.883–3T published elsewhere in this issue of the **Federal Register**].

§ 1.883–5 Effective/applicability dates.

* * * * *

(d) and (e) [The text of the proposed entries for § 1.883–5(d) and (e) is the same as the text of the entries for § 1.883–5T(d) and (e) published elsewhere in this issue of the **Federal Register**].

Par. 3. Section 1.883–1 is amended by revising paragraphs (c)(3)(i)(D), (c)(3)(i)(G), (c)(3)(i)(H), (c)(3)(i)(I), (c)(3)(ii), (g)(1)(ix), (g)(1)(x), (g)(1)(xi), (g)(3), (h)(1)(ii), and (h)(3) to read as follows:

§ 1.883–1 Exclusion of income from the international operation of ships or aircraft.

* * * * *

(c) * * *

(3) * * *

(i) * * *

(D) [The text of the proposed amendment to § 1.883–1(c)(3)(i)(D) is the same as the text of § 1.883–1T(c)(3)(i)(D) published elsewhere in this issue of the **Federal Register**].

* * * * *

(G) through (I) [The text of the proposed amendments to § 1.883–1(c)(3)(i)(G) through (I) is the same as

the text of § 1.883–1T(c)(3)(i)(G) through (I) published elsewhere in this issue of the **Federal Register**].

(ii) [The text of the proposed amendment to § 1.883–1(c)(3)(ii) is the same as the text of § 1.883–1T(c)(3)(ii) published elsewhere in this issue of the **Federal Register**].

* * * * *

(g) * * *

(1) * * *

(ix) through (xi) [The text of the proposed amendments to § 1.883–1(g)(1)(ix) through (xi) is the same as the text of § 1.883–1T(g)(1)(ix) through (xi) published elsewhere in this issue of the **Federal Register**].

* * * * *

(3) [The text of the proposed amendment to § 1.883–1(g)(3) is the same as the text of § 1.883–1T(g)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

(h) * * *

(1) * * *

(ii) [The text of the proposed amendment to § 1.883–1(h)(1)(ii) is the same as the text of § 1.883–1T(h)(1)(ii) published elsewhere in this issue of the **Federal Register**].

(2) * * *

(3) [The text of the proposed amendment to § 1.883–1(h)(3) is the same as the text of § 1.883–1T(h)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

Par. 4. Section 1.883–2 is amended by revising paragraphs (e)(2), (f)(3), and (f)(4)(ii) to read as follows:

§ 1.883–2 Treatment of publicly-traded corporations.

* * * * *

(e) * * *

(2) [The text of the proposed amendment to § 1.883–2(e)(2) is the same as the text of § 1.883–2T(e)(2) published elsewhere in this issue of the **Federal Register**].

(f) * * *

(3) [The text of the proposed amendment to § 1.883–2(f)(3) is the same as the text of § 1.883–2T(f)(3) published elsewhere in this issue of the **Federal Register**].

(4) * * *

(ii) [The text of the proposed amendment to § 1.883–2(f)(4)(ii) is the same as the text of § 1.883–2T(f)(4)(ii) published elsewhere in this issue of the **Federal Register**].

* * * * *

Par. 5. Section 1.883–3 is revised to read as follows:

§ 1.883–3 Treatment of controlled foreign corporations.

[The text of this proposed section is the same as the text of § 1.883–3T published elsewhere in this issue of the **Federal Register**].

Par. 6. Section 1.883–4 is amended by revising paragraphs (d)(4)(i)(C), (d)(4)(i)(D), (e)(2), and (e)(3) to read as follows:

§ 1.883–4 Qualified shareholder stock ownership test.

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) and (D) [The text of the proposed amendments to § 1.883–4(d)(4)(i)(C) and (D) is the same as the text of § 1.883–4T(d)(4)(i)(C) and (D) published elsewhere in this issue of the **Federal Register**].

* * * * *

(e) * * *

(2) and (3) [The text of the proposed amendments to § 1.883–4(e)(2) and (3) is the same as the text of § 1.883–4T(e)(2) and (3) published elsewhere in this issue of the **Federal Register**].

Par. 7. Section 1.883–5 is amended by revising paragraphs (d) and (e) to read as follows:

§ 1.883–5 Effective/applicability dates.

* * * * *

(d) [The text of the proposed amendment to § 1.883–5(d) is the same as the text of § 1.883–5T(d) published elsewhere in this issue of the **Federal Register**].

(e) [The text of the proposed amendment to § 1.883–5(e) is the same as the text of § 1.883–5T(e) published elsewhere in this issue of the **Federal Register**].

Kevin M. Brown,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E7–12037 Filed 6–22–07; 8:45 am]

BILLING CODE 4830–01–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Parts 1190 and 1191

[Docket No. 2007–04]

Accessibility Guidelines for Emergency Transportable Housing

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of intent to establish advisory committee.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) proposes to establish a Federal advisory committee to develop a proposed rule on accessibility guidelines for emergency transportable housing covered by the Americans with Disabilities Act and the Architectural Barriers Act. The Access Board invites comments on the proposal to establish the advisory committee and the proposed committee membership.

DATES: Comments and applications should be received by July 25, 2007.

ADDRESSES: You may submit comments and applications, identified by Docket No. 2007–04, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: mazz@access-board.gov.* Include Docket No. 2007–04 in the subject line of the message.
- *Fax:* (202) 272–0081.
- *Mail or Hand Delivery:* Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., Suite 1000, Washington, DC 20004–1111.

All submissions received must include the agency name and docket number for this rulemaking. Comments will also be available for inspection at the above address from 9 a.m. to 5 p.m. on regular business days.

FOR FURTHER INFORMATION CONTACT: Marsha Mazz, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., Suite 1000, Washington, DC 20004–1111. Telephone number (202) 272–0020 (Voice); (202) 272–0082 (TTY). These are not toll-free numbers. E-mail address: *mazz@access-board.gov.*

SUPPLEMENTARY INFORMATION: The Architectural and Transportation Barriers Compliance Board (Access Board or Board) [1] is responsible for developing accessibility guidelines under the Americans with Disabilities Act (ADA) and the Architectural

[1] The Access Board is an independent Federal agency established by section 502 of the Rehabilitation Act (29 U.S.C. 792) whose primary mission is to promote accessibility for individuals with disabilities. The Access Board consists of 25 members. Thirteen are appointed by the President from among the public, a majority of who are required to be individuals with disabilities. The other twelve are heads of the following Federal agencies or their designees whose positions are Executive Level IV or above: The Departments of Health and Human Services, Education, Transportation, Housing and Urban Development, Labor, Interior, Defense, Justice, Veterans Affairs, and Commerce; General Services Administration; and United States Postal Services.

Barriers Act (ABA) to ensure that newly constructed and altered facilities covered by these laws are readily accessible to and usable by individuals with disabilities. In July 2004, the Access Board published revised accessibility guidelines for facilities covered by the ADA and ABA. 69 FR 44084 (July 23, 2004). The guidelines update accessibility requirements for a wide range of facilities in the public and private sectors. The ADA and ABA Accessibility Guidelines contain ADA scoping (Chapters 1 and 2), ABA scoping (Chapters F1 and F2) and common technical provisions (Chapters 3 through 10) and for the first time contain technical and scoping provisions for both transient lodging and residential dwelling units.

The ADA and ABA Accessibility Guidelines did not anticipate the challenges associated with providing accessible and usable dwelling units which will meet structural and transportation criteria permitting them to be transported across roadways and to be installed in yards or on group trailer sites for emergency use. Therefore, the Access Board wishes to revisit the scoping provisions and technical criteria for residential dwelling units in its guidelines and proposes to establish a Federal advisory committee to develop a proposed rule on this subject. The following interest groups are likely to be affected by accessibility guidelines for emergency transportable housing:

- Federal agencies;
- Organizations representing the needs of individuals with disabilities;
- Trade associations;
- Manufacturers and designers of emergency transportable housing;
- State and local governments; and
- voluntary codes and standards groups.

The Board proposes to appoint the following organizations to represent the interests identified above:

- Advocacy Center.
- Coalition for Citizens with Disabilities.
- Department of Housing and Urban Development.
- Department of Justice.
- Federal Emergency Management Agency.
- Manufactured Housing Institute.
- National Council on Independent Living.
- National Fire Protection Association.
- Recreation Park Trailer Industry Association.
- Recreation Vehicle Industry Association.
- United Spinal Association.

Comments are invited on the proposal to establish the advisory committee and the proposed membership. Organizations that will be affected by the accessibility guidelines for emergency transportable housing and who believe that their interests will not be adequately represented by the above organizations may apply for membership on the committee. Applications should include the following information: (1) The name of the organization and the interest that the organization proposes to represent; (2) the reasons why the organizations specified above do not adequately represent the interests that the organization proposes to represent; (3) evidence that the person submitting the application is authorized to represent the organization; and (4) a written commitment that the organization would participate on the committee in good faith. There is no specific application form. See **ADDRESSES**, above, for information on where and how to submit applications.

To be effective, the size of the committee will be limited. Each organization affected by accessibility guidelines for emergency transportable housing need not have its own representative on the advisory committee. Rather, interests must be adequately represented and the membership must be fairly balanced. After reviewing the comments received in response to this notice and any applications for membership, the Board will issue a notice in the **Federal Register** announcing the establishment of the committee and the committee membership, unless it is determined based on comments that the establishment of the committee would be inappropriate. The first committee meeting is tentatively scheduled for September 24 and 25, 2007 at the Access Board offices in Washington, DC.

The Board expects the committee to hold no more than three meetings and all meetings will be in the Washington, DC area. The meetings will be open to the public. Future committee meetings will be announced in the **Federal Register**. The Board will provide staff support to the committee. Members of the committee will not be compensated for their service. The Board may pay travel expenses for a limited number of persons who would otherwise be unable to serve on the committee. Members will not be considered special government employees since they will serve as representatives of their organizations and will not be required to file confidential financial disclosure reports.

Availability of Copies and Electronic Access

Single copies of this publication may be obtained at no cost by calling the Access Board's automated publications order line (202) 272–0080, by pressing 2 on the telephone keypad and then 1. Please record your name, address, city, State, zip code, telephone number and request the emergency transportable housing advisory committee notice. Persons using a TTY should call (202) 272–0082. This document is available in alternate formats upon request. Persons who want this publication in an alternate format should specify the type of format (cassette tape, Braille, large print, or ASCII disk). This document is also available on the Board's Web site (*http://www.access-board.gov*).

Tricia Mason,

Chair, Architectural and Transportation Barriers Compliance Board.

[FR Doc. E7–12205 Filed 6–22–07; 8:45 am]

BILLING CODE 8150–01–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1196

[Docket No. 2007–03]

RIN 3014–AA22

Passenger Vessel Emergency Alarms Advisory Committee

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of intent to establish advisory committee.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board or Board) proposes to establish a Passenger Vessel Emergency Alarms Advisory Committee (Committee) to make recommendations on issues related to the effectiveness of passenger vessel emergency alarm systems for individuals with hearing loss or deafness. The Access Board invites comments on the proposal to establish the committee and the proposed committee membership.

DATES: Comments and applications should be received by July 25, 2007.

ADDRESSES: You may submit comments and applications, identified by Docket No. 2007–03, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *E-mail: pvag@access-board.gov.* Include Docket No. 2007–03 in the subject line of the message.

• *Fax:* (202) 272–0081.

• *Mail or Hand Delivery:* Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., Suite 1000, Washington, DC 20004–1111.

All submissions received must include the agency name and docket number for this rulemaking. Comments will be available for inspection at the above address from 9 a.m. to 5 p.m. on regular business days.

FOR FURTHER INFORMATION CONTACT: Paul Beatty, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street, NW., Suite 1000, Washington, DC 20004–1111. Telephone number (202) 272–0012 (Voice); (202) 272–0082 (TTY). These are not toll-free numbers. E-mail address: *pvag@access-board.gov.*

SUPPLEMENTARY INFORMATION: The Architectural and Transportation Barriers Compliance Board (Access Board or Board) [1] is responsible for developing accessibility guidelines under the Americans with Disabilities Act (ADA) to ensure that newly constructed and altered passenger vessels covered by the law are readily accessible to and usable by individuals with disabilities.

In July 2006, the Access Board made available for public comment revised draft accessibility guidelines for passenger vessels which are permitted to carry more than 150 passengers or more than 49 overnight passengers. 71 FR 38563 (July 7, 2006). The revised draft guidelines will also apply to all ferries and certain tenders which carry 60 or more passengers. The revised draft guidelines are available on the Board's Web site at *http://www.access-board.gov/pvaac/revised-draft.htm*.

Section V215 of the revised draft guidelines requires that where emergency alarm systems are provided to alert passengers, the alarms in public areas and certain guest rooms must comply with ''principles of best practice.'' This is similar to a provision in the Americans with Disabilities Act and Architectural Barriers Act Accessibility Guidelines (section 702) that permits fire alarm systems in medical care facilities to be provided in accordance with ''industry practice.'' An earlier draft of the passenger vessel guidelines in 2004 required emergency alarm systems (both audible and visible) to be permanently installed and to comply with NFPA 72. 69 FR 69244 (November 26, 2004).

Commenters on the earlier draft primarily focused on the desire to allow portable systems with enhanced capabilities as an alternative to requiring permanently installed visible alarms in public areas and in guest rooms required to have communication features. Aside from problems in interfacing visible alarm systems with public address systems over which audible alarms operate, these commenters noted benefits in using portable systems. Many commenters argued that portable systems would allow technological advances to be more rapidly adopted which could provide better information during emergencies than permanently installed visible alarms. Portable systems would also allow more guest rooms to be covered than the two percent proposed in the 2004 draft. The same portable systems could also be used to communicate other information about shipboard activities more effectively to people who are deaf or hard of hearing. The Board is also aware of how employees on passenger vessels play an important role in providing directions and addressing passenger needs during emergencies. The Board pointed out that this heightened role is more analogous to how hospitals notify their patients and is different from most other facilities on land. As technology in this area is rapidly changing, the revised draft proposed that alarm systems comply with principles of best practice to alert passengers.

Passenger vessel operators, individuals with disabilities, and organizations representing the various interest groups commented that the provision was vague and requested additional guidance. The Board agrees that additional guidance would be helpful and proposes to establish a Passenger Vessel Emergency Alarms Advisory Committee (Committee) to assist in this matter. The committee is expected to make recommendations to the Board on the following issues:

(a) Whether current emergency alarm system designs and practices on passenger vessels meet the access needs of individuals with hearing loss or deafness.

(b) Alternative designs or technologies for emergency alarm systems appropriate for use on passenger vessels that meet the access needs of individuals with hearing loss or deafness.

(c) The contents of proposed accessibility guidelines for passenger vessels related to emergency alarm systems.

The following interest groups are likely to be affected by emergency alarm systems on passenger vessels:

• Individuals with hearing loss or deafness and other individuals with disabilities concerned about emergency alarm systems;

• Passenger vessel operators;

• Manufacturers and designers of emergency alarm systems; and

• Voluntary codes and standards groups which address emergency alarms.

The Board proposes to appoint the following organizations to the committee to represent the interests identified above:

• Community Emergency Preparedness Information Network.

• Cruise Lines International Association.

• Epilepsy Foundation.

• Gallaudet University.

• Hearing Access Program.

• Hearing Loss Association of America.

• National Association of the Deaf.

• National Fire Protection Association.

• Passenger Vessel Association.

• Society of Naval Architects and Marine Engineers.

Comments are invited on the proposal to establish the advisory committee and the proposed membership. Organizations that are affected by emergency alarm systems on passenger vessels and believe that their interests will not be adequately represented by the above organizations may apply for membership on the committee. Applications should include the following information: (1) The name of the organization and the interest that the organization proposes to represent; (2) the reasons why the organizations specified above do not adequately represent the interest that the organization proposes to represent; (3) evidence that the person submitting the application is authorized to represent the organization; and (4) a written commitment that the organization would participate on the committee in good faith. There is no specific application form. See **ADDRESSES**, above,

[1] The Access Board is an independent Federal agency established by section 502 of the Rehabilitation Act (29 U.S.C. 792) whose primary mission is to promote accessibility for individuals with disabilities. The Access Board consists of 25 members. Thirteen are appointed by the President from among the public, a majority of whom are required to be individuals with disabilities. The other twelve are heads of the following Federal agencies or their designees whose positions are Executive Level IV or above: The Departments of Health and Human Services, Education, Transportation, Housing and Urban Development, Labor, Interior, Defense, Justice, Veterans Affairs, and Commerce; General Services Administration; and United States Postal Services.

for information on where and how to submit applications.

To be effective, the size of the committee will be limited. Each organization affected by emergency alarm systems on passenger vessels need not have its own representative on the committee. Rather, each interest must be adequately represented and the membership must be fairly balanced.

After reviewing the comments received in response to this notice and any applications for membership, the Board will issue a notice in the **Federal Register** announcing the establishment of the committee and the committee membership, unless it is determined based on comments that the establishment of the committee would be inappropriate. The first committee meeting is tentatively scheduled for August 15 and 16, 2007 at the Access Board offices in Washington, DC.

The Board expects the committee to hold no more than three meetings and all meetings will be in the Washington, DC area. The meetings will be open to the public. Future committee meetings will be announced in the **Federal Register**.

The Board will provide staff support to the committee. Members of the committee will not be compensated for their service. The Board may pay travel expenses for a limited number of persons who would otherwise be unable to serve on the committee. Members will not be considered special government employees since they will serve as representatives of their organizations and will not be required to file confidential financial disclosure reports.

Availability of Copies and Electronic Access

Single copies of this publication may be obtained at no cost by calling the Access Board's automated publications order line (202) 272–0080, by pressing 2 on the telephone keypad and then please record your name, address, city, State, zip code, telephone number and request the emergency alarms advisory committee notice. Persons using a TTY should call (202) 272–0082. This document is available in alternate formats upon request. Persons who want this publication in an alternate format should specify the type of format (cassette tape, Braille, large print, or ASCII disk). This document is also available on the Board's Web site (*http://www.access-board.gov*).

Tricia Mason,

Chair, Architectural and Transportation Barriers Compliance Board.

[FR Doc. E7–12196 Filed 6–22–07; 8:45 am]

BILLING CODE 8150–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 52

RIN 0925–AA42

Grants for Research Projects

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) proposes to amend the existing regulations governing grants for research projects by revising the definition of Principal Investigator to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of principal investigator to one single individual, and the conditions for multiple or concurrent awards permitting the Secretary to evaluate, approve and make one or more awards pursuant to one or more applications.

DATES: Comments must be received on or before August 24, 2007 in order to assure that NIH will be able to consider the comments in preparing the final rule.

ADDRESSES: Persons and organizations interested in submitting comments, identified by RIN 0925–AA42, may do so by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: jm40z@nih.gov*. Include RIN number 0925–AA42 in the subject line of the message.
- *Fax:* 301–402–0169.
- *Mail:* Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20892.
- *Hand Delivery/Courier:* 6011 Executive Boulevard, Suite 601, Rockville, MD 20892.

FOR FURTHER INFORMATION CONTACT: Jerry Moore at the address above, or telephone 301–496–4607 (not a toll-free number).

SUPPLEMENTARY INFORMATION: On September 30, 2003, NIH Director Elias A. Zerhouni announced a series of far-reaching strategic initiatives known collectively as the NIH Roadmap for Medical Research (NIH Roadmap). The NIH Roadmap is an innovative approach designed to transform the nation's medical research capabilities and accelerate fundamental research discovery and translation of that knowledge into effective prevention strategies and new treatments. One of the NIH Roadmap initiatives encourages interdisciplinary research and team science and includes a recommendation to modify grant and research contract applications to allow proposing of more than one Principal Investigator when appropriate. This is congruent with the January 4, 2005, directive issued by the President's Office of Science and Technology Policy (OSTP) to all Federal research agency heads instructing the heads to accommodate the recognition of two or more Principal Investigators on research projects (grants and contacts). While this new OSTP policy does not prohibit the use of a single Principal Investigator when that is most appropriate for a particular research project, it simply permits the designation of more than one Principal Investigator when that more accurately reflects the management needs of a research project.

For the purpose of implementing the NIH Roadmap initiatives, the NIH plans to modify research grant and contract applications to request information on more than one Principal Investigator, consistent with the new OSTP policy establishing the appropriateness of multiple Principal Investigators. Accordingly, we propose to revise the definition of the term Principal Investigator set forth in § 52.2 of the Grants for Research Projects regulations codified at 42 CFR Part 52, and the conditions for multiple or concurrent awards permitting the Secretary to evaluate, approve and make one or more awards pursuant to one or more applications.

Specifically, in this Notice of Proposed Rulemaking (NPRM) we propose to amend the existing regulations governing grants for research projects by revising the definition of Principal Investigator so that it does not limit the role of Principal Investigator to one single individual.

As announced in NIH notice number NOT–OD–07–017 (*http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-017.html*), these individual(s) must be

judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant in order to be considered Principal Investigator(s). While this rule would permit the applicant organization to designate multiple individuals as Principal Investigators who share the authority and responsibility for leading and directing the project, intellectually and logistically, each Principal Investigator is responsible and accountable to the applicant organization (or, as appropriate, to a collaborating organization), for the proper conduct of the project or program, including the submission of all required reports. In other words, the presence of more than one identified Principal Investigator on an application or award diminishes neither the responsibility nor the accountability of any individual Principal Investigator.

Additionally, we propose to amend § 52.6 by revising paragraph (d) permitting the Secretary to evaluate, approve and make one or more awards pursuant to one or more applications.

Under current regulations, the Secretary is permitted to evaluate, approve and make more than one award pursuant to two or more applications. In some cases, however, it may be desirable to disaggregate a single application to make more than one award. For example, in the case of an application for support of a project that involves more than one Principal Investigator affiliated with more than one institution, it may be desirable to administer the project with more than one award. In addition, applications that involve subprojects may be disaggregated into separate awards to improve scientific management. The revised regulatory language clarifies options and provides an opportunity to contemplate more than one award that may involve more than one institution in response to a single application. In some of these cases separate records will be associated in the NIH data system so that the components can be managed as a single project to promote close collaboration with their counterparts. Actual awards also will be associated through special terms of award to clearly note collaborations and any special requirements resulting from such collaborations, In other cases, it may be appropriate to consider multiple applications from more than one institutions that are managed as a single unit with multiple awards to the different institutions to facilitate collaboration. This change will foster interdisciplinary and collaborative research and will improve management flexibility even when components of such collaborative research programs are administered by different NIH awarding components.

The purpose of this NPRM is to invite public comment on the proposed regulation. The following is provided as public information.

Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate, and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If a regulatory action is deemed to fall within the scope of the definition of the term ''significant regulatory action'' contained in § 3(f) of the Order, prepublication review by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) is necessary. This proposed rule was reviewed under Executive Order 12866 by OIRA and was deemed significant.

Executive Order 12866 also requires each agency to write all rules in plain language. In addition to your substantive comments on this proposed rule, we invite comments on how to make this proposed rule easier to understand. For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that is not clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Could we improve clarity by adding illustrative examples, tables, lists, or diagrams?
- What else could we do to make the rule easier to understand.?

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6) requires that regulatory proposals be analyzed to determine whether they create a significant impact on a substantial number of small entities. The Director, NIH, certifies that any final rule resulting from this proposed rule will not have any such impact.

Executive Order 13132

Executive Order 13132, Federalism, requires that federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. The Director, NIH, reviewed the proposed rule as required under the Executive Order and determined that it does not have any federalism implications. The Director, NIH, certifies that the proposed rule will not have an effect on the States, or on the distribution of power and responsibilities among the various levels of government.

Paperwork Reduction Act

This proposed rule does not contain any information collection requirements which are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbered programs affected by the proposed regulations are:

93.113—Biological Response to Environmental Health Hazards
93.114—Applied Toxicological Research and Testing
93.115—Biometry and Risk Estimation-Health Risks from Environmental Exposures
93.118—Acquired Immunodeficiency Syndrome (AIDS) Activity
93.121—Oral Diseases and Disorders Research
93.135—Centers for Research and Demonstration for Health Promotion and Disease Prevention
93.136—Injury Prevention and Control Research and State and Community Based Programs
93.172—Human Genome Research
93.173—Research Related to Deafness and Communication Disorders
93.184—Disabilities Prevention
93.213—Research and Training in Complementary and Alternative Medicine
93.242—Mental Health Research Grants
93.262—Occupational Safety and Health Program
93.271—Alcohol Research Career Development Awards for Scientists and Clinicians
93.273—Alcohol Research Programs
93.279—Drug Abuse and Addiction Research Programs
93.281—Mental Health Research Career/Scientist Development Awards
93.283—Centers for Disease Control and Prevention-Investigations and Technical Assistance
93.361—Nursing Research
93.389—National Center for Research Sources
93.390—Academic Research Enhancement Award
93.393—Cancer Cause and Prevention Research
93.394—Cancer Detection and Diagnosis Research

93.395—Cancer Treatment Research
93.396—Cancer Biology Research
93.821—Biophysics and Physiological Sciences Research
93.837—Heart and Vascular Diseases Research
93.838—Lung Diseases Research
93.839—Blood Diseases and Resources Research
93.846—Arthritis, Musculoskeletal and Skin Diseases Research
93.847—Diabetes, Endocrinology and Metabolism Research
93.848—Digestive Diseases and Nutrition Research
93.849—Kidney Diseases, Urology and Hematology Research
93.853—Clinical Research Related to Neurological Disorders
93.855—Allergy, Immunology and Transplantation Research
93.856—Microbiology and Infectious Diseases Research
93.859—Biomedical Research and Research Training
93.865—Research for Mothers and Children
93.866—Aging Research
93.867—Vision Research
93.879—Medical Library Assistance
93.929—Center for Medical Rehabilitation Research
93.934—Fogarty International Center Research Collaboration Award
93.939—Blood Diseases and Resources Research
93.941—HIV Demonstration, Research, Public and Professional Education Projects
93.942—Research, Treatment and Education Programs on Lyme Disease in the United States
93.943—Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups
93.947—Tuberculosis Demonstration, Research, Public and Professional Education

List of Subjects in 42 CFR Part 52

Grant programs—Health; Medical research; Occupational safety and health.

Dated: May 11, 2006.

Elias A. Zerhouni,

Director, National Institutes of Health.

Approved: October 12, 2006.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received by the Office of the Federal Register on June 20, 2007.

For reasons presented in the preamble, it is proposed to amend part 52 of title 42 of the Code of Federal Regulations as set forth below.

PART 52—GRANTS FOR RESEARCH PROJECTS

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 216.

1A. We propose to amend § 52.2 by revising the definition of the term ''Principal investigator'' to read as follows:

§ 52.2 Definitions.

* * * * *

Principal investigator means the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project.

* * * * *

2. We propose to amend *§ 52.6 by revising paragraph (d) to read as follows:*

§ 52.6 Grant awards.

* * * * *

(d) *Multiple or concurrent awards.* Whenever a research project involves a number of different but related problems, activities or disciplines which require evaluation by different groups, or whenever support for a project could be more effectively administered by separate handling of separate aspects of the project, the Secretary may evaluate, approve and make one or more awards pursuant to one or more applications.

* * * * *

[FR Doc. E7–12223 Filed 6–22–07; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition To List the Sierra Nevada Distinct Population Segment of the Mountain Yellow-Legged Frog (Rana muscosa)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of an amended 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce an amended 12-month finding on a petition to list the Sierra Nevada distinct population segment (DPS) of the mountain yellow-legged frog (*Rana muscosa*) under the Endangered Species Act of 1973, as amended (Act). We are amending our previous 12-month petition finding, which found that listing is warranted but precluded, by revising the preclusion and expeditious progress section of that finding.

DATES: The finding announced in this document was made on June 25, 2007.

ADDRESSES: Supporting documentation used in the development of this amended 12-month finding will be available for inspection, by appointment, during normal business hours at the Endangered Species Program, Division of Conservation and Classification, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 420, Arlington, VA 22203. Comments and materials received, as well as supporting documentation used in the development of the initial 12-month finding published on January 16, 2003 (68 FR 2283), are available for inspection, by appointment, during normal business hours at the Sacramento Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room W–2605, Sacramento, CA 95825.

FOR FURTHER INFORMATION CONTACT: Chris Nolin, Chief, Division of Conservation and Classification, Endangered Species Program (see **ADDRESSES** section) (telephone 703–358–2171). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), requires that, for any petition to revise the Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information that the petitioned action may be warranted, we make a finding within 12 months of the date of the receipt of the petition on whether the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted, but that the immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether any species is threatened or endangered, and expeditious progress is being made to add or remove qualified species from the Lists of Endangered and Threatened Wildlife and Plants (Lists). Such 12-

month findings are to be published promptly in the **Federal Register.** In addition, section 4(b)(3)(C) of the Act requires that a petition for which the requested action is found to be warranted but precluded shall be treated as though resubmitted on the date of such finding, requiring a subsequent finding to be made within 12 months; we refer to such findings as ''resubmitted petition findings.''

Biological Information and Summary of Factors Affecting the Species

Our initial 12-month finding, published in the **Federal Register** on January 16, 2003 (68 FR 2283), included information on the biology, status, and summary of factors affecting the species. This information has been updated annually through our Candidate Notice of Review (CNOR), in which we evaluate the available scientific information and make our resubmitted petition findings on this and other species for which we previously have made a 12-month finding that listing is warranted but precluded. The most recent CNOR was published on September 12, 2006 (71 FR 53756); in it we continued to find that listing the Sierra Nevada DPS of the mountain yellow-legged frog is warranted but precluded, based on the latest species assessment for this taxon. That assessment, which provides the most current information on the biology, status, and summary of factors affecting the species, is available on our Internet Web site at *http://www.fws.gov/endangered/candidates/index.html.* We are currently reviewing and evaluating the available information on this taxon and will again update our species assessment and resubmitted petition finding in the next CNOR, which we anticipate we will publish in fall 2007, unless we take some other listing action pertaining to the Sierra Nevada DPS of the mountain yellow-legged frog prior to that time.

Previous Federal Actions

On February 10, 2000, we received a petition, dated February 8, 2000, from the Center for Biological Diversity and Pacific Rivers Council to list the Sierra Nevada population of the mountain yellow-legged frog stating that the Sierra Nevada population of the mountain yellow-legged frog satisfies the criteria in our Distinct Population Segment (DPS) Policy and that it should be listed as endangered. On October 12, 2000, we published a 90-day finding on that petition in the **Federal Register** (65 FR 60603), concluding that the petition presented substantial scientific or commercial information to indicate that the listing of the Sierra Nevada population of the mountain yellow-legged frog may be warranted; we also requested information and data regarding the species. On January 10, 2003, we made a 12-month petition finding that listing was warranted but precluded, and we published the 12-month finding in the **Federal Register** on January 16, 2003 (68 FR 2283). We made this finding in accordance with a court order requiring us to complete a finding by January 10, 2003 (*Center for Biological Diversity* v. *Norton,* No. 01–2106 (N. D. Cal. Dec. 12, 2001)). Upon publication of that finding, we added the Sierra Nevada DPS of the mountain yellow-legged frog to our list of species that are candidates for listing.

The Center for Biological Diversity and the Pacific Rivers Council challenged our finding that listing was warranted but precluded, and sought to compel the Service to proceed with listing the frog. On June 21, 2004, the U.S. District Court for the Eastern District of California granted summary judgment in favor of the United States (*Center for Biological Diversity* v. *Norton*, No. 03–01758 (E. D. Cal. June 21, 2004)). In response to an appeal of the decision, on October 18, 2006, the 9th Circuit Court of Appeals reversed and remanded the District Court's judgment. Specifically, the 9th Circuit Court of Appeals concluded that the 12-month finding we published on January 16, 2003, did not meet the requirements of section 4(b)(3)(B) of the Act, because the finding did not contain information demonstrating that: (1) The immediate proposal and timely promulgation of a final regulation implementing the petitioned action is precluded by pending proposals to determine whether any species is an endangered species or a threatened species; and (2) expeditious progress is being made to add qualified species to either of the Lists and to remove from such Lists species for which the protections of the Act are no longer necessary (*Center for Biological Diversity* v. *Kempthorne,* 466 F.3d 1098, 1103 (9th Cir. Oct. 18, 2006)).

We are addressing the 9th Circuit Court's ruling by amending our January 16, 2003, warranted but precluded finding to include a description and evaluation of the reasons and data demonstrating why listing the Sierra Nevada DPS of the mountain yellow-legged frog was precluded and describing the expeditious progress we had made on adding qualified species to the Lists at the time we published the 12-month finding.

Preclusion and Expeditious Progress

Preclusion is a function of the listing priority of a species in relation to the resources that are available and competing demands for those resources. Thus, in any given fiscal year (FY), multiple factors dictate whether it will be possible to undertake work on a proposed listing regulation or whether promulgation of such a proposal is warranted but precluded by higher priority listing actions.

The resources available for listing actions are determined through the annual Congressional appropriations process. The appropriation for the Listing Program is available to support work involving the following listing actions: Proposed and final listing rules; 90-day and 12-month findings on petitions to add species to the Lists or to change the status of a species from threatened to endangered; resubmitted petition findings; proposed and final rules designating critical habitat; and litigation-related, administrative, and program management functions (including preparing and allocating budgets, responding to Congressional and public inquiries, and conducting public outreach regarding listing and critical habitat). The work involved in preparing various listing documents can be extensive and may include, but is not limited to: gathering and assessing the best scientific and commercial data available and conducting analyses used as the basis for our decisions; writing and publishing documents; and obtaining, reviewing, and evaluating public comments and peer review comments on proposed rules and incorporating relevant information into final rules. The number of listing actions that we can undertake in a given year also is influenced by the complexity of those listing actions, i.e., more complex actions generally are more costly. For example, during the past several years, the cost (excluding publication costs) for preparing a 12-month finding, without a proposed listing rule, has ranged from approximately $11,000 for one species with a restricted range and involving a relatively uncomplicated analysis, to $305,000 for another species that is wide-ranging and involved a complex analysis.

We cannot spend more than is appropriated for the Listing Program without violating the Anti-Deficiency Act (31 U.S.C. 1341(a)(1)(A)). In addition, in FY 1998 and for each fiscal year since then, Congress has placed a statutory cap on funds which may be expended for the Listing Program, equal to the amount expressly appropriated

for that purpose in that fiscal year (see H.R. 2107, 105th Cong. (1997)). This cap was designed to prevent funds appropriated for other functions under the Act, or for other Service programs, from being used for Listing Program actions (see H.R. No. 105–163, at 21, 25 (1997)).

Recognizing that designation of critical habitat for species already listed would consume most of the overall Listing Program appropriation, Congress also put a critical habitat subcap in place in FY 2002 and has retained it each subsequent year to ensure that some funds are available for other work in theListing Program: ''The critical habitat designation subcap will ensure that some funding is available to address other listing activities'' (H.R. Rep. No. 107–103, at 30 (2001). In FY 2002 and each year since then, the Service has had to use virtually the entire critical habitat subcap to address court-mandated designations of critical habitat, and consequently none of the critical habitat subcap funds have been available for other listing activities.

Thus, through the listing cap, the critical habitat subcap, and the amount of funds needed to address court-mandated critical habitat designations, Congress and the courts have in effect determined the amount of money available for other listing activities. Therefore, the funds in the listing cap, other than those needed to address court-mandated critical habitat for already listed species, set the limits on our determinations of preclusion and expeditious progress.

Congress also recognized that the availability of resources was the key element in deciding whether, when making a 12-month petition finding, we would prepare and issue a listing proposal or make a ''warranted but precluded'' finding for a given species. The Conference Report No. 835 accompanying Public Law 97–304, which established the current statutory deadlines and the warranted but precluded finding, states (in a discussion on 90-day petition findings that by its own terms also covers 12-month findings) that the deadlines were ''not intended to allow the Secretary to delay commencing the rulemaking process for any reason other than that the existence of pending or imminent proposals to list species subject to a greater degree of threat would make allocation of resources to such a petition [i.e., for a lower-ranking species] unwise'' (H.R. Conf. Rep. No. 97–835, at 21 (1982)). Taking into account the information presented above, in FY 2003 (the fiscal year in which we made our initial warranted but precluded finding for this population of the mountain yellow-legged frog), the outer parameter within which ''expeditious progress'' must be measured is that amount of progress that could be achieved by spending $3,077,000, which was the amount available in the Listing Program appropriation that was not within the critical habitat subcap.

Our process is to make our determinations of preclusion on a nationwide basis to ensure that the species most in need of listing will be addressed first and also because we allocate our listing budget on a nationwide basis. However, through court orders and court-approved settlements, Federal district courts have mandated that we must complete certain listing activities with respect to specified species and have established the schedules by which we must complete those activities. The species involved in these court-mandated listing activities are not always those that we have identified as being most in need of listing. As described below, a large majority of the $3,077,000 appropriation available in FY 2003 for new listings of species was consumed by court-mandated listing activities; by ordering or sanctioning these actions the courts essentially determined that these were the highest priority actions to be undertaken with available funding. Copies of the court orders and settlement agreements referred to below are available from the Service (see **ADDRESSES** section above) and are part of the administrative record for this resubmitted petition finding.

The FY 2003 appropriation of $3,077,000 for listing activities (i.e., the portion of the Listing Program funding not related to critical habitat designations for species that already are listed) was fully allocated to fund work in the following categories of actions in the Listing Program (see Table below): Compliance with court orders and court-approved settlement agreements requiring that petition findings or listing determinations be completed by a specific date; section 4 (of the Act) listing actions with absolute statutory deadlines; essential litigation-related, and administrative- and program-management functions; and a few high-priority listing actions.

FY 2003 LISTING ALLOCATION

	Allocated	Available balance
FY03 Appropriation	$3,077,000	$3,077,000
Capability Funding (Regional Office staff salaries)	700,000	2,377,000
Economic Analysis*	9,805	2,367,195
FEDERAL REGISTER Printing	188,700	2,178,495
Attorney Fee Awards and Litigation	39,496	2,138,999
General Program Activities (funds used primarily for work on 90-day and 12-month petition findings required by statute, or by court-order or settlement agreements; also for limited work on proposed rules; also includes Washington Office salaries)	2,138,999	0

* Funds used for work on critical habitat associated with a proposed listing determination for Scotts Valley polygonum.

In FY 2003, our allocation of Listing Program funds included a limited amount of funding ($100,000) to each Regional office to ensure that the office maintained minimal core capacity for listing actions (e.g., evaluating the status of species to help ensure that an emergency listing action can be taken if necessary, participating in work to meet the statutory requirement to annually review and make findings on resubmitted petitions). In a Region that faces a relatively limited workload in the Listing Program with regard to deadlines resulting from court orders or settlement agreements, and a relatively limited workload related to meeting statutory deadlines, some of this ''capability'' funding may be available to address high priority listing actions. However, in most Regions the limited amount of capability funding for Regional offices included in an allocation is used for work associated with supporting listing actions related to court orders or settlement agreements, and for meeting statutory

deadlines (i.e., there are no funds available for high priority listing actions).

Based on the available funds and their allocation for these purposes, no FY 2003 funds were available for proposed listing actions for any species, including the Sierra Nevada DPS of the mountain yellow-legged frog, except for those with court-ordered deadlines and for the Miami blue butterfly (see explanation below for why we worked on a proposed rule for this species). Specific details regarding the individual actions taken using the FY 2003 funding, which precluded our ability to undertake a listing proposal for the Sierra Nevada DPS of the mountain yellow-legged frog, are provided below. As noted below, in some instances, the work was based on meeting deadlines established by court order or by settlement agreements. In other instances, the work was done in order to meet statutory deadlines. All 12-month findings are subject to an unqualified statutory deadline. With regard to 90-day findings, the decision in *Biodiversity Legal Foundation* v. *Badgley*, 309 F.3d 1166 (9th Cir. 2002), held that the Act requires that 90-day petition findings (i.e., the initial finding as to whether a petition contains substantial information, which the Act directs us to make within 90 days of receipt of a petition, if practicable) must be made no later than 12 months after receipt of the petition, regardless of whether it is practicable to do so. Thus, all 90-day findings are arguably subject to an absolute statutory deadline. As a result of this ruling, which changed our interpretation of section 4(b)(3) of the Act, we have been working to issue petition findings on outstanding petitions.

Our decision that a proposed rule to list the Sierra Nevada DPS of the mountain yellow-legged frog was warranted but precluded, included consideration of its listing priority. In accordance with guidance we published on September 21, 1983, we assign a listing priority number (LPN) to each candidate species (48 FR 43098). Such a priority ranking guidance system is required under section 4(h)(3) of the Act (16 U.S.C. 1533(h)(3)). Using this guidance, we assign each candidate a LPN of 1 to 12, depending on the magnitude of threats, imminence of threats, and taxonomic status; the lower the listing priority number, the higher the listing priority (e.g., a species with a LPN of 1 would have the highest listing priority). At the time we made our 12-month finding (68 FR 2283, January 16, 2003), we assigned the Sierra Nevada DPS of the mountain yellow-legged frog a LPN of 3 based on threats that were of a high magnitude and imminent, and on its taxonomic status as a distinct population segment. Thus, listing this population of the frog was precluded by the more than 80 candidate species that had higher listing priority (LPN = 2) at the time of our petition finding (see Table 1 of the Notice of Review; 67 FR 40657, June 13, 2002), in addition to being precluded by lack of available funds.

As explained above, a determination that listing is warranted but precluded also must demonstrate that expeditious progress is being made to add and remove qualified species to the Lists. (We note that in this amended finding we do not discuss specific actions taken on progress towards removing species from the Lists because that work is conducted using appropriations for our Recovery program, a separately-budgeted component of the Endangered Species Program. As explained above in our description of the statutory cap on Listing Program funds, the Recovery Program funds and actions supported by them cannot be considered in determining expeditious progress made in the Listing Program.) As with our ''precluded'' finding, expeditious progress in adding qualified species to the Lists is a function of the resources available and the competing demands for those funds. Our expeditious progress in FY 2003 in the Listing Program, up to the date we published the 12-month finding for the Sierra Nevada DPS of the mountain yellow-legged frog, included preparing and publishing the following:

(1) Final rule to list *Lomatium cookii* (Cook's lomatium) and *Limnanthes floccosa* (large-flowered woolly meadowfoam) (67 FR 68004, November 7, 2002). The deadline for this action was the result of a court-approved settlement agreement.

(2) Withdrawal of a proposed rule to list the flat-tailed lizard as threatened (68 FR 331, January 3, 2003). The deadline for this listing decision was the result of a court order.

(3) 12-month petition finding for the Yosemite toad (67 FR 75834, December 10, 2002). The deadline for this action was the result of a court-approved settlement agreement.

(4) 90-day petition findings for three species: Washington population of the western gray squirrel (67 FR 65931, October 29, 2002) (deadline set by a court order), Mono basin population of the greater sage-grouse (67 FR 78811, December 26, 2002) (statutory deadline), and cerulean warbler (67 FR 65083, October 23, 2002) (statutory deadline).

Our expeditious progress also included work on listing actions for 55 species for which decisions had not been completed as of the date we published our initial 12-month finding for the Sierra Nevada population of the mountain yellow-legged frog. These actions are listed below; work on those actions with an asterisk (*) was conducted pursuant to a deadline set by a court and all other actions, with the exception of the work on a proposed listing for the Miami blue butterfly, were pursuant to meeting statutory timelines, i.e., timelines required under the Act:

(1) *90-day petition findings for the following species:* New England cottontail, greater/eastern sage-grouse, western sage-grouse*, mountain quail*, trumpeter swan, Colorado River cutthroat trout, and midvalley fairy shrimp*.

(2) *12-month petition findings for the following species:* Western gray squirrel*, Queen Charlotte goshawk*, California spotted owl*, Kootenai river burbot*, westslope cutthroat trout*, *Horkelia hendersonii* (Henderson's horkelia)*, and *Lupinus lepidus* var. *ashlandensis* (Mt. Ashland lupine)*.

(3) *Proposed listing determinations for the following species:* California tiger salamander (rangewide)*, Salt Creek tiger beetle (deadline subject to an out-of-court settlement agreement), and Miami blue butterfly. We worked on a proposed rule to list the Miami blue butterfly as it was a high priority listing action. The Miami blue butterfly is restricted to one isolated population on Bahia Honda Key in Florida and is threatened by the combined influences of catastrophic environmental events, habitat destruction or modification, mosquito control activities, potential illegal collection, potential loss of genetic heterogeneity, and potential predation. Work on assessing the status of the species and preparing a listing rule originally was approved for funding and was initiated in FY 2003 because at the time, the Region considered that it was an emergency. We later decided not to exercise our discretion under section 4(b)(7) to emergency list the species (based in part on the existence of a captive-bred population). However, because a review of the species had been conducted, and because it was a high priority species, continued work on the proposed listing was approved.

(4) *Final listing determinations for the following species:* Florida black bear*, pygmy rabbit, mountain plover*, Rota bridled white-eye*, California tiger salamander (Sonoma County)*, slickspot peppergrass*, Scott Valley polygonum (with critical habitat), and three Mariana Island plants (*Nesogenes*

rotensis, Osmoxylon mariannense, and *Tabernaemontana rotensis*)*.

(5) Resubmitted petition findings for 30 species (these species are identified with the code ''C*'' in Table 1 of the CNOR published in the **Federal Register** (67 FR 40657, June 13, 2002)).

We have endeavored to make our listing actions as efficient and timely as possible, given the requirements of the relevant laws and regulations, and constraints relating to workload and personnel. We are continually considering ways to streamline processes or achieve economies of scale, such as by batching related actions together where feasible. Given our limited budget for implementing section 4 of the Act, the actions described above collectively constitute expeditious progress.

Conclusion

The information provided above amends our finding, published January 16, 2003 (68 FR 2283), that listing the Sierra Nevada DPS of the mountain yellow-legged frog is warranted but precluded. Specifically, the information amends the finding to include information pertaining to preclusion and expeditious progress. Thus this amended finding fully satisfies the requirements of section 4(b)(3)(B)(iii) of the Act. We note also that since publication of our initial warranted but precluded finding, we have made resubmitted petition findings pursuant to the requirement of section 4(b)(3)(C)(i) of the Act, and published these in the **Federal Register** on May 4, 2004 (69 FR 24875), May 11, 2005 (70 FR 24869), and September 12, 2006 (71 FR 53755). In each case we have found that the petitioned action is warranted but precluded, and our finding has included information demonstrating preclusion and expeditious progress.

We will continue to monitor the status of this species and its habitat. Should an emergency situation develop, we will act to provide immediate protection, if warranted. We intend that any proposed listing action for the Sierra Nevada DPS of the mountain yellow-legged frog will be as accurate as possible. Therefore, we will continue to accept additional information and comments from all concerned governmental agencies, the scientific community, industry, or any other interested party concerning the status of this species.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: June 14, 2007.

Kenneth Stansell,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. E7–12282 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 224

[I.D. 021607C]

Endangered and Threatened Species; Proposed Endangered Status for the Cook Inlet Beluga Whale; Public Hearing

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearing.

SUMMARY: On April 20, 2007, NMFS proposed the listing of the Cook Inlet beluga whale as an endangered species under the Endangered Species Act of 1973 (ESA). As part of that proposal, NMFS announced a public comment period to end on June 19, 2007, and then extended the comment period to August 3, 2007. NMFS has received requests for public hearings on this issue. In response, NMFS announced two public hearings to be held in Alaska in a previous **Federal Register** notice. In addition, NMFS is announcing a separate hearing in this notice that will be held in Silver Spring, Maryland, in order to provide greater opportunity for public comment.

DATES: The hearing will be held on July 31, 2007, from 3:30 to 6:30 p.m. in Silver Spring, MD. Written comments must be received by August 3, 2007.

ADDRESSES: The July 31, 2007, hearing will be held at NOAA Headquarters, Building 2, Conference Room 2358, 1325 East-West Highway, Silver Spring, MD.

Written comments can be sent to Kaja Brix, Assistant Regional Administrator, Protected Resources Division, Alaska Region, NMFS, Attn: Ellen Sebastian. Comments may be submitted by:

- E-mail: *CIB-ESA-Endangered@noaa.gov*. Include in the subject line the following document identifier: Cook Inlet Beluga Whale PR. E-mail comments, with or without attachments, are limited to 5 megabytes.
- Webform at the Federal eRulemaking Portal: *www.regulations.gov*. Follow the instructions at that site for submitting comments.
- Mail: P. O Box 21668, Juneau, AK 99802.
- Hand delivery to the Federal Building : 709 W. 9th Street, Juneau, AK.
- Fax: (907) 586–7557.

FOR FURTHER INFORMATION CONTACT: For specific information regarding the July 31, 2007, hearing in Silver Spring, MD, contact Chris Uyeda, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3226, telephone (301) 713–1401 . For all other information regarding the proposed listing of the Cook Inlet beluga whale contact Brad Smith, NMFS, 222 West 7th Avenue, Anchorage, AK 99517, telephone (907) 271–5006; Kaja Brix, NMFS, (907) 586–7235; or Marta Nammack, (301) 713–1401.

SUPPLEMENTARY INFORMATION:

Background

On April 20, 2007, NMFS published a proposed rule (72 FR 19854) to list the Cook Inlet beluga whale as an endangered species under the Endangered Species Act of 1973 (ESA), as amended. This action followed completion of the Cook Inlet beluga whale status review, which found this population to be at risk of extinction within the next 100 years and described NMFS' determination that this population constitutes a ''species'', or distinct population segment under the ESA.

On June 13, 2007, in response to requests, NMFS announced that two public hearings would be held in Alaska regarding the proposed listing of the Cook Inlet beluga whale (72 FR 32605). Following this announcement, NMFS received an additional request for a public hearing to be held in Silver Spring. This request was submitted beyond the 45–day statutory deadline for public hearing requests (16 U.S.C. 1533(b)(5)(E)). However, NMFS has decided to voluntarily honor the request in order to provide additional opportunities for public comment.

Public Hearings

Joint Commerce-Interior ESA implementing regulations state that the Secretary shall promptly hold at least one public hearing if any person requests one within 45 days of publication of a proposed regulation to list a species or to designate critical habitat (see 50 CFR 424.16(c)(3)). In past ESA rule-makings NMFS has conducted traditional public hearings, consisting of recorded oral testimony from interested individuals. This format, although providing a means for public input,

does not provide opportunities for dialogue and information exchange. NMFS believes that the traditional public hearing format can be improved upon by also including a brief presentation on the results of the Cook Inlet beluga Status Review and other topics of interest.

The preferred means for providing public comment to the official record is via written testimony prepared in advance of the meeting which may also be presented orally. Blank ''comment sheets'' will be provided at the meetings for those without prepared written comments, and opportunity will also be provided for additional oral testimony. There is no need to register for these hearings.

In scheduling these public hearings, NMFS has anticipated that many affected stakeholders and members of the public may prefer to discuss the proposed listing directly with staff during the public comment period. However, these public meetings are not the only opportunity for the public to provide input on this proposal. The public and stakeholders are encouraged to continue to comment and provide input to NMFS on the proposal (via correspondence, e-mail, and the Internet; see **ADDRESSES**) up until the scheduled close of the comment period on August 3, 2007.

References

The proposed rule, status review, maps, a list of the references cited in this document, and other materials relating to the proposed listing can be found on the NMFS Alaska Region website *http://www.fakr.noaa.gov/*.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: June 19, 2007.

James H. Lecky,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. E7–12262 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 72, No. 121
Monday, June 25, 2007

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 20, 2007.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Poultry Market News Report.
OMB Control Number: 0581–0033.
Summary of Collection: The Agricultural Marketing Act of 1946, legislates that USDA shall ''collect and disseminate marketing information * * *'' and ''* * * collect, tabulate, and disseminate statistics on marketing agricultural products, including, but not restricted to statistics on marketing supplies, storage, stocks, quantity, quality, and condition of such products in various positions in the marketing channel, use of such products, and shipments and unloads thereof.'' The mission of Market New is to provide current unbiased, factual information to all members of the Nation's agricultural industry, from farm to retailer.
Need and Use of the Information: Information is used by the private sector to make economic decisions to establish market values for application in contracts or settlement value, and to address specific concerns or issues related to trade agreements and disputes as well as being used by educational institutions, specifically, agricultural colleges and universities. Government agencies such as the Foreign Agricultural Service, Economic Research Service and the National Agricultural Statistics Service use market news data in the performance of their missions. Also, the poultry and egg industry uses the data to help determine future production and marketing projections. The absence of these data would deny primary and secondary users information that otherwise would be available to aid them in their production and marketing decisions, analyses, research and knowledge of current market conditions. The omission of these data could adversely affect prices, supply, and demand.
Description of Respondents: Business or other for-profit; farms.
Number of Respondents: 1,785.
Frequency of Responses: Reporting: Weekly; monthly.
Total Burden Hours: 18,422.

Agricultural Marketing Service

Title: Regulations for Voluntary Grading of Poultry Products and Rabbit Products, 7 CFR part 70.
OMB Control Number: 0581–0127.
Summary of Collection: The Agricultural Marketing Act of 1946 (60 Stat. 1087–1091, as amended; 7 U.S.C. 1621–1627) (AMA) directs and authorizes the Department to develop standards of quality, grades, grading programs, and services to enable a more orderly marketing of agricultural products so trading may be facilitated and so consumers may be able to obtain products graded and identified under USDA programs. Regulations in 7 CFR part 70 provide for a voluntary program for grading poultry and rabbits on the basis of U.S. classes, standards and grades. The Agricultural Marketing Service (AMS) carries out the regulations, which provide a voluntary program for grading poultry and rabbit products.
Need and Use of the Information: This is a voluntary program on a fee for service basis. Respondents need to request or apply for the specific service they want and in doing so they provide information. The information is needed to administer the program, assess the cost of providing service, and to assure graded poultry and rabbits are properly labeled. Without this information the agency could not ensure properly labeled poultry and rabbit products and the integrity of the USDA grade mark if each new label was not submitted for approval.
Description of Respondents: Business or other for profit; farms.
Number of Respondents: 359.
Frequency of Responses: Reporting: On occasion; semi-annually; monthly; annually; Other: Daily.
Total Burden Hours: 1,813.

Agricultural Marketing Service

Title: Export Fruit Regulations.
OMB Control Number: 0581–0143.
Summary of Collection: Fresh apples and grapes grown in the United States shipped to any foreign destination must meet minimum quality and other requirements established by regulations issued under the Export Apple Act (7 CFR part 33) and the Export Grape and Plum Act (7 CFR part 35). These Acts were designed to promote the foreign trade of the United States in apples and grapes; to protect the reputation of these American-grown commodities; and to prevent deception or misrepresentation of the quality of such products moving in foreign commerce. Currently, plum and pear provisions are not covered under the Export Grape and Plum Act.

The regulation issued under the Export Grape and Plum Act (7 CFR part 35) covers fresh grapes grown in the United States and shipped to foreign destinations, except Canada and Mexico.

Need and Use of the Information: Persons who ship fresh apples and grapes grown in the U.S. to foreign destinations must have such shipment inspected and certified by Federal or Federal-State Inspection Service (FSIS) inspectors. Agriculture Marketing Service administers the FSIS. Official FSIS inspection certificates and phytosanitary certificates issued by USDA's Animal and Plant Health Inspection Service provide the needed information for USDA. Export carriers are required to keep on file for three years copies of inspection certificates for apples and grapes.

Description of Respondents: Business or other for-profit; farms.

Number of Respondents: 100.

Frequency of Responses: Recordkeeping; reporting; on occasion, monthly, annually.

Total Burden Hours: 25.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E7–12260 Filed 6–22–07; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 20, 2007.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Noninsured Crop Disaster Assistance Program.

OMB Control Number: 0560–0175.

Summary of Collection: The Noninsured Crop Assistance Program (NAP) is authorized under 7 U.S.C. 7333 and implemented under regulations issued at 7 CFR Part 1437. The collection of crop planting and production data is necessary for the Commodity Credit Corporation (CCC) to calculate the producer's approved yield on the basis of actual production history. Information collection relative to the occurrence of crop damage or loss production and application for Noninsured Crop Disaster Assistance Program (NAP) is necessary for CCC to accept and consider a request for assistance under NAP and to facilitate eligibility determinations. NAP provides eligible producers of eligible crops with protection to the catastrophic risk protection plan of crop insurance. It helps reduce production risks faced by producers of crops for which Federal crop insurance is not available. It also reduces financial losses that occur when natural disasters cause a catastrophic loss of production or prevented planting of an eligible crop. The Farm Service Agency (FSA) will collect information using several forms.

Need and Use of the Information: FSA will collect the producer's name, address identification number, farm and tract, acreage, ownership, location, crop history, planted acreage, production, yield, share, etc. The information will be used to identify eligible NAP participants, acreage and location, crop and commodities. If information is not collected FSA will not be able to identify and determine eligible participants and crops being planted or produced, or provide assistance to agricultural producers who as a result of natural disaster have suffered catastrophic losses of agricultural crops or commodities.

Description of Respondents: Individuals or household.

Number of Respondents: 291,500.

Frequency of Responses: Recordkeeping; Reporting: On occasion; Weekly; monthly; annually.

Total Burden Hours: 2,143,562.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. E7–12261 Filed 6–22–07; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2006–0076]

Availability of an Environmental Assessment and Finding of No Significant Impact for a Biological Control Agent for Old World Climbing Fern

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the release of a nonindigenous gall mite, *Floracarus perrepae,* for the biological control of Old World climbing fern, *Lygodium microphyllum,* in the continental United States. Based on its finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

FOR FURTHER INFORMATION CONTACT: Dr. Robert V. Flanders, Chief, Pest Permit Evaluation Branch, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1228; (301) 734–5930.

SUPPLEMENTARY INFORMATION:

Background

Old World climbing fern, *Lygodium microphyllum,* is a climbing fern that has a large native range that extends through much of the Old World tropics. It has become established in central and southern peninsular Florida, where it grows in a number of wetland and mesic (having a moderate supply of moisture) habitats including hammocks, cypress swamps, flatwoods, bayheads, and disturbed sites.

The climbing fern is a highly invasive, exotic weed that climbs over plants, including tall trees, to form massive walls of vegetation. It also forms thick mats on the ground that smother native plants. New infestations can arise great distances from existing populations because the weed produces millions of spores that are spread by wind and other physical carriers. A single spore is capable of starting a new infestation. In addition, dense strands of Old World climbing fern present a major fire hazard.

The biocontrol agent that is the subject of this notice, *Floracarus perrepae,* is a gall mite in the insect family Eriophyidae and is native to Australia and tropical Asia. The adult mites feed on young leaflets of the target weed, *L. microphyllum,* inducing the leaf margins to curl into galls. Female mites lay an average 60 eggs inside a gall. The eggs hatch in 5 days and immature mites feed on the specialized tissue within the gall, requiring 4 days to become adults. Galled leaflets are often infected by secondary ambient pathogens and have reduced life spans. Plants infested with the mite have slower rates of growth than uninfested plants.

The mite is also host specific. Host specificity tests conducted in Australia indicate that *F. perrepae* is specific to only two *Lygodium* species (the target weed *L. microphyllum* and the Australian fern *Lygodium reticulatum*).

On May 23, 2006, we published in the **Federal Register** (71 FR 29607–29608, Docket No. APHIS–2006–0076) a notice [1] in which we announced the availability, for public review and comment, of an environmental assessment (EA) that examined the potential environmental impacts associated with the proposed release of this biological control agent into the continental United States.

We solicited comments on the EA for 30 days ending June 22, 2006. We did not receive any comments by that date.

In this document, we are advising the public of our finding of no significant impact (FONSI) regarding the release of the nonindigenous gall mite *F. perrepae* as a biological control agent to reduce the severity and extent of Old World climbing fern infestation in the continental United States. The finding, which is based on the EA, reflects our determination that release of this biological control agent will not have a significant impact on the quality of the human environment.

The EA and FONSI may be viewed on the Regulations.gov Web site (see footnote 1). Copies of the EA and FONSI are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

The EA and FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Done in Washington, DC, this 19th day of June 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–12240 Filed 6–22–07; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the notice, environmental assessment, and finding of no significant impact, go to *http://www.regulations.gov*, click on the ''Advanced Search'' tab, and select ''Docket Search.'' In the Docket ID field, enter APHIS–2006–0076, then click ''Submit.'' Clicking on the Docket ID link in the search results page will produce a list of all documents in the docket.

DEPARTMENT OF AGRICULTURE

Forest Service

Mendocino Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Mendocino County Resource Advisory Committee (RAC) will meet July 20, 2007 in Willits, California. Agenda items to be covered include: (1) Approval of minutes, (2) Public Comment, (3) Extension of RAC (4) Discussion—items of interest (5) Discussion/approval of projects, (6) next agenda items and meeting date.

DATES: The meeting will be held on July 20, 2007, from 9 a.m. to 12 noon.

ADDRESSES: The meeting will be held at the Mendocino County Museum, located at 400 E. Commercial St., Willits, California.

FOR FURTHER INFORMATION CONTACT: Roberta Hurt, Committee Coordinator, USDA, Mendocino National Forest, Covelo Ranger District, 78150 Covelo Road, Covelo, CA 95428. (707) 983–8503; email *rhurt@fs.fed.us.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Persons who wish to bring matters to the attention of the Committee may file written statements with the Committee staff by July 10, 2007. Public will have the opportunity to address the committee at the meeting.

Dated: June 14, 2007.

Jim Ruhl,

Designated Federal Official.

[FR Doc. 07–3073 Filed 6–22–07; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Purchase of Mid-Iowa (IA) and Amendment to Its Area

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice.

SUMMARY: Grain Inspection, Packers and Stockyards Administration (GIPSA) designated Intercontinental Grain Inspection Inc. (Intercontinental), a subsidiary of Societe Generale de Surveillance (SGS) North America Inc., to provide domestic official inspection services under the United States Grain Standards Act, as amended (USGSA). Intercontinental's designation terminates September 30, 2007, therefore; GIPSA asked interested persons to submit an application for designation in the March 7, 2007, **Federal Register** (72 FR 10138). However, SGS North America Inc. purchased Mid-Iowa Grain Inspection, Inc. (Mid-Iowa), a currently designated agency providing official inspection services. Intercontinental will be merged into Mid-Iowa. Accordingly, GIPSA is not proceeding further with the request for applications for designation in the Corpus Christi, Texas, area, which is currently designated to Intercontinental. The designation of Mid-Iowa has been amended to include this geographic area.

DATES: *Effective Date:* July 1, 2007.

FOR FURTHER INFORMATION CONTACT: Karen Guagliardo at 202–720–7312, e-mail *Karen.W.Guagliardo@usda.gov.*

SUPPLEMENTARY INFORMATION: Section 7(f)(1) of the United States Grain Standards Act, as amended (USGSA), authorizes GIPSA's Administrator to designate a qualified applicant to provide official services in a specified

area after determining that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)(1)). GIPSA designated Intercontinental, headquarters in Corpus Christi, Texas, to provide official inspection services under the Act effective July 20, 2006, and terminating September 30, 2007.

Section 7(g)(1) of USGSA provides that designations of official agencies will terminate not later than three years and may be renewed according to the criteria and procedures prescribed in Section 7(f) of USGSA. Intercontinental's designation ends September 30, 2007, according to USGSA. In the March 7, 2007, **Federal Register** (72 FR 10138), GIPSA asked persons interested in providing official services in the area served by Intercontinental to submit an application for designation. However, SGS North America Inc., the company that currently owns Intercontinental, advised GIPSA that they purchased Mid-Iowa, a currently designated official agency, and that Intercontinental will be merged into Mid-Iowa. Accordingly, GIPSA is not proceeding further with the request for applications for designation published in the March 7, 2007, **Federal Register**. GIPSA is amending Mid-Iowa's designation due to the ownership change of Intercontinental.

Pursuant to Section 7(f)(2) of the Act, the following geographic area, in the State of Texas will now be assigned to Mid-Iowa.

- Bounded on the north by the northern Young, Jack, Montague, Cooke, Grayson, Fannin, Lamar, Red River, Morris, and Marion County line east to the Texas State line;
- Bounded on the east by the eastern Texas State line south to the southern Texas State line;
- Bounded on the south by the southern Texas State line west to the western Val Verde County line;
- Bounded on the west by the western Val Verde, Edwards, Kimble, Mason, San Saba, Mills, Comanche, Eastland, Stephens, and Young County lines north to the northern Young County line.

Mid-Iowa's assigned geographic area does not include the export port locations inside Mid-Iowa's area which are serviced by GIPSA.

Effective July 1, 2007, Mid-Iowa's present geographic area is amended to include the state of Texas. Mid-Iowa's current designation to provide official inspection services terminates June 30, 2008. Official services may be obtained by contacting Mid-Iowa at 319–363–0239.

Authority: 7 U.S.C. 71 *et seq.*

David R. Shipman,

Acting Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. E7–12095 Filed 6–22–07; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: U.S. Census Bureau.

Title: Boundary and Annexation Survey (BAS).

Form Number(s): BAS 1, BAS 2, BAS 3, BAS 4, BAS 5, BAS 6, BAS–ARF1, and BAS–ARF2; 6 Respondent Guides; and 21 Letters.

Agency Approval Number: 0607–0151.

Type of Request: Revision of a currently approved collection.

Burden Hours: 145,750.

Number of Respondents: 34,000.

Average Hours per Response: 4 hours and 30 minutes.

Needs and Uses: The U.S. Census Bureau is requesting the clearance of forms to continue the Boundary and Annexation Survey (BAS). The BAS documents the following actions by governmental units:

—The creation of newly incorporated places and minor civil divisions (MCDs)
—The creation of new counties, and the addition of new federally recognized American Indian areas (AIAs) (American Indian Areas include reservations and/or off-reservation trust lands and tribal subdivisions)
—The dissolution of incorporated places and MCDs
—The changes in the boundaries of incorporated places, MCDs, counties, barrios, subbarrios, municipios, consolidated cities, and AIANNHAs (American Indian, Alaska Native, Native Hawaiian Areas include reservations and/or off-reservation trust lands and tribal subdivisions, Alaska Native Regional Corporations (ANRCs) and Hawaiian home lands).

The results of the BAS provide geographic information to support the following products and/or services:

—Decennial and economic censuses
—American Community Survey
—Population Estimates Program
—OMB Circular A–16 Responsibilities for:
—Geospatial One Stop E–GOV Initiative
—Federal Geographic Data Committee (FGDC) Responsibilities for:
—FGDC Subcommittee on Cultural and Demographic Data
—Boundaries
—U.S. Geological Survey (USGS) Initiative on The National Map
—Federal Information Processing Standards (FIPS) program
—Geographic Names Information Systems (GNIS) program

The BAS also fulfills the requirements specified in Title 13, United States Code, Section 6.

In past decades, the BAS mailing universe varied depending on the year. However, starting in 2008, the Census Bureau will include all governments in the universe to support the 2010 Decennial Census and the other programs mentioned above. To minimize time and cost, the BAS will mail only those governments with legal boundary changes and, will not be sent to governments with no changes.

We have revised and added to the option to submissions methods. The following information describes the methods that participants can use to respond to the BAS, including electronic response options as required by the E-government initiative:

Paper BAS

Participants are provided with paper maps and forms to update their boundary and geographic information. If the participant does not respond during Advance Response, they will automatically be enrolled in the traditional paper BAS method.

Web-BAS

Every year in January, participants will receive a user name and password. This password will be used to access a Web site through a web browser (such as, Internet Explorer, Netscape or Firefox). The Web-BAS site lets the user submit changes according to specific business rules and constraints set by the Census Bureau.

MAF/TIGER Partnership Software (MTPS)

MTPS is a PC-based software application for participants to update Census Bureau maps and forms, as well as local contact data. Participants receive a CD containing the software to install on their computer, one or more CD(s) containing the data for their entity and the surrounding area, and a user name and password to access the data in the software. Participants will be able to submit the map and form updates

using this software. A CD writer is required to return the data.

Digital BAS

Digital BAS is designed to accept submissions from experienced geographic information system (GIS) users. Digital BAS participants modify spatial data provided by the Census Bureau to digitally submit boundary and feature updates. Participants must follow the same requirements that are part of Web-BAS and MTPS.

Visit the BAS Web site at *http://www.census.gov/geo/www/bas/bashome.html* for more information on each of these methods.

The data and information collected from the BAS serves Federal, State, local, and tribal governments, and the private sector. The BAS is the primary provider for the following services and products:

—Data collection for the decennial and economic censuses, and annual surveys
—Primary data of new municipal incorporations and disincorporations
—Legal boundary changes for governmental units
—Inventory for the FIPS and GNIS programs
—Updates of population estimates for governments including: The creation of new governments; the dissolution of governments; or changes in boundaries for local or tribal governments
—Legal boundary framework layer for the FGDC National Spatial Data Infrastructure, the USGS National Map, and the E–GOV Geospatial One Stop.

Affected Public: State, local or tribal government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C., Section 6.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax 202–395–7245 or e-mail *bharrisk@omb.eop.gov.*

Dated: June 18, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–12210 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: U.S. Census Bureau.

Title: Current Industrial Reports (CIR) Program (Wave II—Mandatory and Voluntary).

Form Number(s): M311J, M313N, M313P, M327G, MQ311A, MQ313A, MQ315A, MQ325A, MQ325F, MQ333W, MA311D, MA314Q, MA321T, MA325G, MA333N, MA333P, MA335E, MA335J, and MA336G.

Agency Approval Number: 0607–0395.

Type of Request: Revision of a currently approved collection.

Burden: 10,859 hours.

Number of Respondents: 8,152.

Average Hours per Response: 35 minutes.

Needs and Uses: The U.S. Census Bureau is requesting a revision of the mandatory and voluntary surveys in Wave II of the Current Industrial Reports (CIR) program. The Census Bureau conducts a series of monthly, quarterly, and annual surveys as part of the CIR program. The CIR program focuses primarily on the quantity and value of shipments data of particular products and occasionally with data on production and inventories; unfilled orders, receipts, stocks, and consumption; and comparative data on domestic production, exports, and imports of the products they cover. Due to the large number of surveys in the CIR program, for clearance purposes, the CIR surveys are divided into ''waves.'' One wave is resubmitted for clearance each year. This year the Census Bureau is submitting mandatory and voluntary surveys of Wave II for clearance.

During the economic census years, years ending in 2 and 7 all voluntary annual surveys are made mandatory. For the 2007 Economic Census the following surveys are converting to mandatory status: *MA311D*—''Confectionery'', *MA333N*—''Fluid Power Products for Motion Control (Including Aerospace), and *MA336G*—''Aerospace Industry''. *MA334M* was moved to ''Consumer Electronics'' and *MA334Q*, ''Semiconductors, Electronic Components and Semiconductor Manufacturing Equipment'' to another wave. Also, we are discontinuing *MQ335C*—''Fluorescent Lamp Ballasts'' because manufacturing activities are located outside the United States.

Primary users of these data are government and regulatory agencies, business firms, trade associations, and private research and consulting organizations. The Federal Reserve Board (FRB) uses CIR data in its monthly index of industrial production as well as its annual revision to the index. The Bureau of Economic Analysis (BEA) and the Bureau of Labor Statistics (BLS) use the CIR data in the estimate of components of gross domestic product (GDP) and the estimate of output for productivity analysis, respectively. Many government agencies, such as the International Trade Commission, Department of Agriculture, Food and Drug Administration, Department of Energy, Federal Aviation Administration, BEA, and International Trade Administration use the data for industrial analysis, projections, and monitoring import penetration. Private business firms and organizations use the data for trend projections, market analysis, product planning, and other economic and business-oriented analysis. Since the CIR program is the sole, consistent source of information regarding specific manufactured products in the intercensal years, the absence thereof would severely hinder the Federal Government's ability to measure and monitor important segments of the domestic economy, as well as the effect of import penetration.

Affected Public: Business or other for-profit organizations.

Frequency: Monthly, quarterly, and annually.

Respondent's Obligation: This request contains both voluntary and mandatory surveys.

Legal Authority: Title 13 U.S.C., Sections 61, 81, 131, 182, 224, 225.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dhynek@doc.gov*).

Written comments and recommendations for the proposed

information collection should be sent within 30 days of publication of this notice to Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: June 18, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–12212 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security (BIS).

Title: Reporting and Recordkeeping Requirements Under the Wassenaar Arrangement.

Agency Form Number: None.

OMB Approval Number: 0694–0106.

Type of Request: Extension of a currently approved collection of information.

Burden Hours: 20.

Average Time per Response: 1 minute to 15 minutes per response.

Number of Respondents: 35.

Needs and Uses: To fulfill U.S. commitments to the Wassenaar Arrangement with regard to dual-use items, Section 743 of the Export Administration Regulations imposes reporting and recordkeeping requirements for license exception exports of certain items controlled under the Wassenaar Arrangement.

Affected Public: Business or other for-profit organizations, not for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, e-mail address, *David_Rostker@omb.eop.gov*, or fax number, (202) 395–7285.

Dated: June 18, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–12213 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security (BIS).

Title: Written Assurances for Exports of Technical Data Under License Exception Technology and Software Under Restriction.

Agency Form Number: None.

OMB Approval Number: 0694–0023.

Type of Request: Extension of a currently approved collection of information.

Burden Hours: 258.

Average Time per Response: 31 minutes.

Number of Respondents: 500.

Needs and Uses: This collection is required by the Export Administration Regulations (EAR) Section 740.6 that requires exporters to obtain letters of assurance from their importers stating that technology or software will not be reexported or released to unauthorized destinations that are subject to controls for national security or foreign policy and nuclear non-proliferation reasons. The importer, in making these assurances acknowledges his/her requirement to comply with the EAR. The written assurance requirement of License Exception TSR (Technology and Software under Restriction) provides greater security for the protection of U.S. origin technology and software that becomes incorporated into foreign products.

Affected Public: Businesses or other for-profit organizations.

Respondent's Obligation: Required to obtain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, email address, *David_Rostker@omb.eop.gov*, or fax number, (202) 395–7285.

Dated: June 18, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–12217 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Census Coverage Measurement Person Interview and Reinterview Operations

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration written comments must be submitted on or before August 24, 2007.

ADDRESSES: Direct all comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Magdalena Ramos, U.S. Census Bureau, 4600 Silver Hill Rd., Room 4H265, Washington, DC 20233, 301–763–4295 (or via the Internet at *Magdalena.Ramos@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

In preparation for the 2010 Census, the U.S. Census Bureau will conduct Census Coverage Measurement (CCM) activities, part of the 2008 Census Dress Rehearsal. The 2008 Census Dress Rehearsal will be conducted in two

sites, one urban, and the other one, a mix of urban and suburban. San Joaquin County, California is the urban site. South Central North Carolina has been selected as the urban/suburban mix site. The North Carolina site consists of Fayetteville and nine counties surrounding Fayetteville (Chatham, Cumberland, Harnett, Hoke, Lee, Montgomery, Moore, Richmond, and Scotland). As is typical, the CCM operations and activities will be conducted separate from and independent of the census operations. The CCM program for the dress rehearsal is designed to ensure that all planned coverage measurement operations are working as expected, that they are integrated internally, and that they are coordinated with the appropriate census operations. This is particularly important because the dress rehearsal is the first time in the 2010 census cycle that CCM operations for housing units will be conducted. The CCM operations planned for the dress rehearsal, to the extent possible, will mirror those that will be conducted for the 2010 Census to provide estimates of *net coverage error* and *coverage error components* (omissions and erroneous enumerations) for housing units and persons in housing units (see Definition of Terms). The data collection and matching methodologies for previous coverage measurement programs were designed only to measure net coverage error, which reflects the difference between omissions and erroneous inclusions.

The 2008 CCM survey sample is a multi-phase probability sample of housing units comprising a number of distinct processes from forming block clusters for the two sites, selecting sample block clusters where the CCM survey will be conducted, to eventually selecting addresses for interviewing. Two samples will be selected to measure census coverage of housing units and the household population: The population sample (P sample) and the enumeration sample (E sample). The P sample is a sample of housing units and persons obtained independently from the census for a sample of block clusters, while the E sample is a sample of census housing units and enumerations in the same block cluster as the P sample.

The independent roster of housing units is obtained during the CCM Independent Listing Operation, the results of which will be matched to census housing units in the sample block clusters and surrounding blocks. After the CCM Independent Listing and matching operations have taken place, some cases with discrepancies between the CCM Independent Listing and the Census will be identified to receive the CCM Housing Unit Followup interview. The results of this interview will again be matched to the list of census housing units. The results of the housing unit matching operations will be used to determine which CCM and Census addresses will be eligible to go to the CCM Person Interview (PI) Operation. After data collected from the CCM PI is matched to data collected by the Census, some cases with discrepancies between the CCM PI and the Census will be sent for another CCM interview called the CCM Person Followup operation. A separate **Federal Register** Notice has already been issued for the CCM Independent Listing and CCM Housing Unit Followup operations. A **Federal Register** Notice will be issued for the CCM Person Followup Operation.

For each sample block cluster, we will conduct a CCM PI for selected housing units. During CCM PI, interviewers will use a computer-assisted data collection instrument on a hand held computer to obtain information about the current residents of the sample housing unit including those who may have moved into the selected housing unit since Census Day (April 1, 2008), and certain persons who moved out of the sample housing unit between Census Day and the time of the CCM interview. We will include nonmatched Census addresses in the CCM PI so we can ascertain their census enumeration status earlier than if they were included in the Person Followup operation conducted later in the CCM processing.

The CCM PI operation will collect the information listed below only for persons in housing units. We are not studying coverage measurement for other types of living quarters (for example, group quarters) in the 2008 CCM Dress Rehearsal. The automated CCM PI instrument will collect the following information for selected housing units:

1. Roster of people living at the housing unit at the time of the CCM PI Interview.
2. Census Day (April 1, 2008) address information for people who moved into the sample address since Census Day.
3. Other addresses where a person may have been counted on Census Day.
4. Information to determine where each person should be counted on Census Day (relative to our residence rules). For example, interviewers will probe for persons who might have been left off the household roster; ask additional questions about persons who moved from another address on Census Day to the sample address; collect additional information for persons with multiple addresses.
5. Demographic information for each person in the household on Interview Day or Census Day, including name, date of birth, age, sex, Hispanic Origin, race, and relationship.
6. Name and above information for any person who has moved out of the sample address since Census Day (if known).

The CCM PI Reinterview is a quality control operation that will be conducted on 10 percent of the PI cases. The purpose of the operation is to confirm that the CCM PI interviewer conducted a CCM PI interview with a household member or a proxy respondent and to conduct the complete CCM PI interview as needed if the original interview seems questionable.

II. Method of Collection

The CCM PI and Reinterview operations will be conducted using a computer-assisted data collection instrument on a hand-held computer. The CCM PI will be conducted through personal interviews while the CCM PI Reinterview interviews will be conducted by telephone and personal interviews.

The CCM PI and PI Reinterview operations will occur starting August 22, 2008 through October 10, 2008.

Definition of Terms

Components of Coverage Error—The two components of census coverage error are census omissions (missed persons or housing units) and erroneous inclusions (persons or housing units enumerated in the census that should not have been). Examples of erroneous inclusions are: housing units built after Census Day and persons or housing units enumerated more than once (duplicates).

Net Coverage Error—Reflects the difference between census omissions and erroneous inclusions. A positive net error indicates an undercount, while a negative net error indicates an over-count.

For more information about the 2008 Census Dress Rehearsal please visit the following page of the Census Bureau's Web site: *http://www.census.gov/2010census/2008_dress_rehearsal/*.

III. Data

OMB Number: None.
Form Number: None.
Type of Review: Regular submission.
Affected Public: Individuals or households.
Estimated Number of Respondents: 14,375 addresses for PI and 1,438 addresses for PI Reinterview.

Estimated Times per Response: 10 minutes.

Estimated Total Annual Burden Hours: 2,636.

Estimated Total Annual Cost to the Public: $0.

Respondent Obligation: Mandatory.

Legal Authority: Title 13, U.S. Code, Sections 141, 193, and 221.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the information collection; they also will become a matter of public record.

Dated: June 18, 2007.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E7–12208 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

[Docket No. 18–2006]

Foreign-Trade Zones Board

Foreign-Trade Zone 47—Boone County, KY; Withdrawal of Application for Subzone Status adidas Sales, Inc. (Apparel, Footwear, and Sporting Equipment)

Notice is hereby given of the withdrawal of the application requesting special-purpose subzone status for the warehousing and distribution facilities of adidas Sales, Inc. The application was filed on April 28, 2006 (71 FR 26925, 5–9–2006).

The withdrawal was requested because of changed circumstances, and the case has been closed without prejudice.

Dated: June 19, 2007.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E7–12269 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–892]

Carbazole Violet Pigment 23 From the People's Republic of China: Notice of Rescission, in Part, of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 25, 2007.

FOR FURTHER INFORMATION CONTACT: Charles Riggle or Marin Weaver, Import Administration, Room 1870, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0650 and (202) 482–2336, respectively.

Background

On December 1, 2006, the Department of Commerce (''the Department'') published a notice of opportunity to request an administrative review of the antidumping duty order on carbazole violet pigment 23 from the People's Republic of China (''PRC''). *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation: Opportunity to Request Administrative Review,* 71 FR 69543, (December 1, 2006). On December 29, 2006, Nation Ford Chemical Company and Sun Chemical Company (''Petitioners'') requested that the Department conduct an administrative review of Aesthetic ColorTech (Shanghai) Co. Ltd., Anhui Worldbest Import and Export Co. Ltd., Cidic Company Ltd., Ganguink Group, Pigment Division, Gold Link Industries Co. Ltd., Hunan Sunlogistics International Co. Ltd. Shanghai Branch, Hygeia-Chem (Shanghai) Co. Ltd., Nantong Haidi Chemical Co. Ltd., Pudong Prime International Logistics Inc., Shanghai Rainbow Dyes Import and Export Co. Ltd., Sinocol Corporation Ltd., Trust Chem Company Ltd., and Yangcheng Tiacheng Chemical Co. Ltd. On January 4, 2007, Trust Chem Company Ltd. also requested an administrative review of its exports. The Department published a notice of initiation of the antidumping duty administrative review of carbazole violet pigment 23 from the PRC for the period December 1, 2005, through November 30, 2006, covering the firms named above. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 72 FR 5005 (February 2, 2007). On May 2, 2007, Petitioners withdrew their request for an administrative review for Gold Link Industries Co. Ltd. and Nantong Haidi Chemical Co. Ltd. On May 3, 2007, Petitioners withdrew their request for an administrative review for Aesthetic ColorTech (Shanghai) Co. Ltd., Anhui Worldbest Import and Export Co. Ltd., Cidic Company Ltd., Ganguink Group, Pigment Division, Hunan Sunlogistics International Co. Ltd. Shanghai Branch, Hygeia-Chem (Shanghai) Co. Ltd., Pudong Prime International Logistics Inc., Shanghai Rainbow Dyes Import and Export Co. Ltd., Sinocol Corporation Ltd., and Yangcheng Tiacheng Chemical Co. Ltd. Petitioners were the sole requesters of an administrative review for these twelve companies.

Rescission of Review, in Part

The Department's regulations at 19 CFR 351.213(d)(1) provide that the Department will rescind an administrative review if the party that requested the review withdraws its request for review within 90 days of the date of publication of the notice of initiation of the requested review, or withdraws its request at a later date if the Department determines that it is reasonable to extend the time limit for withdrawing the request. Petitioner withdrew its request within the 90-day deadline. Therefore, we are rescinding this review of the antidumping duty order on carbazole violet pigment 23 from the PRC covering the period December 1, 2005, through November 30, 2006, for Gold Link Industries Co. Ltd., Nantong Haidi Chemical Co. Ltd., Aesthetic ColorTech (Shanghai) Co. Ltd., Anhui Worldbest Import and Export Co. Ltd., Cidic Company Ltd., Ganguink Group, Pigment Division, Hunan Sunlogistics International Co. Ltd. Shanghai Branch, Hygeia-Chem (Shanghai) Co. Ltd., Pudong Prime International Logistics Inc., Shanghai Rainbow Dyes Import and Export Co. Ltd., Sinocol Corporation Ltd., and Yangcheng Tiacheng Chemical Co. Ltd. The Department will issue appropriate assessment instructions directly to U.S. Customs and Border Protection 15 days of publication of this rescission in part. We are not rescinding the review with respect to Trust Chem Company Ltd.

Notification Regarding APOs

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues

to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with section 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: June 11, 2007.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 07–3103 Filed 6–22–07; 8:45 am]

BILLING CODE 3510–05–M

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before July 25, 2007.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation'']. '' Persons submitting comments electronically should not submit paper copies.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: June 20, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Postsecondary Education

Type of Review: New.

Title: Title VI International Research and Studies Program.

Frequency: Annually.

Affected Public: Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 100.

Burden Hours: 10,000.

Abstract: This is an application to participate in the International Research and Studies program, which provides grants to conduct research and studies to improve and strengthen instruction in modern foreign languages, area studies, and other international fields.

This information collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collections (1890–0001). Therefore, the 30-day public comment period notice will be the only public comment notice published for this information collection.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3384. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E7–12257 Filed 6–22–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–39–002]

Black Marlin Pipeline Company; Notice of Motion To Place Settlement Rates into Effect on an Interim Basis

June 18, 2007.

Take notice that on June 12, 2007, Black Marlin Pipeline Company tendered for filing to become part of its FERC Gas Tariff, Original Volume No. 1, Substitute Fifteenth Revised No. 4, to be effective May 1, 2007, subject to certain conditions.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before the date as indicated below. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on June 22, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12177 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–487–000]

Cheyenne Plains Gas Pipeline Company, LLC; Notice of Proposed Changes in FERC Gas Tariff

June 15, 2007.

Take notice that on June 12, 2007, Cheyenne Plains Gas Pipeline Company, LLC (Cheyenne Plains) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, Seventh Revised Sheet No. 1 to become effective June 23, 2007.

Cheyenne Plains states that the tariff sheet is being filed to submit a new contract to the list of non-conforming agreements for the Commission's information and review.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12190 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–488–000]

Columbia Gas Transmission Corporation; Notice of Tariff Filing and Non-Conforming Service Agreement

June 15, 2007.

Take notice that on June 12, 2007, Columbia Gas Transmission Corporation (Columbia) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No.1, Nineteenth Revised Sheet No. 500B, with an effective date of June 13, 2007.

Columbia also tendered for filing the following non-conforming Service Agreement for consideration and approval:

FTS Service Agreement No. 94274, Between Columbia Gas Transmission Corporation and BP Energy Company, Dated June 11, 2007.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12185 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP07–396–000]

Gulf South Pipeline Company, LP; Notice of Request Under Blanket Authorization

June 18, 2007.

Take notice that on June 8, 2007, Gulf South Pipeline Company, LP (Gulf South), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, filed in Docket No. CP07–396–000, a prior notice request pursuant to sections 157.205 and 157.208 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act for authorization to construct, own, and operate two new compressor stations on its existing natural gas transmission pipeline facilities in Mobile County, Alabama, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Specifically, Gulf South proposes to construct, own, operate, and maintain two new compressor stations, the Whistler Junction Compressor Station (Whistler Junction) and the Airport Junction Compressor Station (Airport Junction) in Mobile County, Alabama, to satisfy the growing demand for natural gas in the Southeastern United States. These compressor stations are designed to deliver, on a firm basis, 250,000 Dth per day to Gulfstream Natural Gas System, L.L.C. (Gulfstream), an interstate pipeline, at an existing interconnect near Coden, Alabama in Mobile County. Whistler Junction will consist of one 4,680 horsepower Solar Centaur 40–4700S turbine engine equipped with Solar's ''SoLoNO$_X$'' system. Airport Junction will consist of one 4,735 horsepower Caterpillar G3616 TALE reciprocating engine equipped with a low-NO$_X$ burner system. A new office and controls building will also be constructed. No wetlands are impacted by the project. All construction will be contained within Gulf South's property. Gulf South will finance the facilities with funds on hand. The estimated cost of the facilities is $22,985,103.

Any questions regarding the application should be directed to J. Kyle Stephens, Vice President, Regulatory Affairs, Gulf South Pipeline Company, LP, 20 East Greenway Plaza, Suite 1000, Houston Texas 77046, or call at (713) 479–8033.

Any person or the Commission's Staff may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to section 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12182 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–176–136]

Natural Gas Pipeline Company of America; Notice of Negotiated Rate

June 15, 2007.

Take notice that on June 13, 2007, Natural Gas Pipeline Company of America (Natural) tendered for filing an amendment to an existing negotiated rate arrangement on file with the Commission, to be effective June 13, 2007.

Natural states that copies of the filing are being mailed to all parties set out on the Commission's official service list.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12187 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator or Foreign Utility Company Status

June 18, 2007.

	Docket no.
Navasota Odessa Energy Partners LP	EG07–41–000
Navasota Wharton Energy Partners LP	EG07–42–000
Sleeping Bear, LLC	EG07–43–000
Altura Power L.P.,	EG07–44–000
Hidroelectrica El Chocon S.A.	FC07–12–000
Centrales Termicas Mendoza S.A.	FC07–13–000
Centrales Termicas San Nicolas, S.A.	FC07–14–000
CMS Ensenada S.A.	FC07–16–000
Terasen Gas Inc.	FC07–19–000
Terasen Gas (Vancouver Island) Inc.	FC07–20–000
CMS (India) Operation & Maintenance Company Private Limited	FC07–21–000
CMS International Operating Company	FC07–22–000
ST-CMS Electric Company Private Limited	FC07–23–000
Jorf Lasfar Energy Company SCA	FC07–24–000
Shuweihat O&M Limited Partnership	FC07–25–000

	Docket no.
Jubail Energy Company	FC07–26–000
CMS Morocco Operating Company SCA	FC07–27–000
Shuweihat CMS International Power Company	FC07–28–000
Takoradi International Company	FC07–29–000

Take notice that during the month of May 2007, the status of the above-captioned entities as Exempt Wholesale Generators or Foreign Utility Companies became effective by operation of the Commission's regulations. 18 CFR 366.7(a).

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12180 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP06–89–002]

Northern Natural Gas Company; Notice of Compliance Filing

June 18, 2007.

Take notice that on June 1, 2007, Northern Natural Gas Company (Northern), tendered for filing in its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets, to be effective August 1, 2007:

Tenth Revised Sheet No. 1
13 Revised Sheet No. 275
Revised Sheet No. 53
Original Sheet No. 165
Original Sheet No. 166
Original Sheet No. 167
Sheet No. 168
First Revised Fifth Revised Sheet No. 403
First Revised Fifth Revised Sheet No. 403A
Second Revised Sheet No. 461
First Revised Sheet No. 462

Northern states that the above sheets are being filed to comply with Commission requirements issued in its April 10, 2007 order in Docket Nos. CP06–89 *et al.* related to the abandonment by sale of the West Hugoton facilities.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed on or before the date as indicated below. Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on June 25, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12181 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–489–000]

Tuscarora Gas Transmission Company; Notice of Proposed Changes in FERC Gas Tariff

June 15, 2007.

Take notice that on June 13, 2007, Tuscarora Gas Transmission Company (Tuscarora) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets to become effective July 16, 2007:

First Revised Sheet No. 101,
Second Revised Sheet No. 102,
First Revised Sheet No. 108,
First Revised Sheet No. 110,
First Revised Sheet No. 111,
Second Revised Sheet No. 112,
First Revised Sheet No. 116,
Second Revised Sheet No. 117

Tuscarora states that a copy of this filing has been served on Tuscarora's jurisdictional customers and interested state regulatory agencies.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12186 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OA07–4–001]

UNS Electric, Inc.; Notice of Compliance Filing Amendment

June 18, 2007.

Take notice that on May 31, 2007, UNS Electric, Inc. (UNS), tendered for filing an amendment to its compliance filing with Order No. 890 in the above-referenced proceeding. UNS states that the two tariff sheets contained in Exhibit A did not contain the proposed changes to sections 19.3 and 19.7 of its OATT.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant and all the parties in this proceeding.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on June 22, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12178 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP07–395–000]

Wyoming Interstate Company, Ltd; Notice of Application

June 15, 2007.

Take notice that on June 6, 2007, Wyoming Interstate Company, Ltd. (WIC), Post Office Box 1087, Colorado Springs, Colorado 80944, filed in Docket No. CP07–395–000, an application pursuant to section 7(c) of the Natural Gas Act (NGA), requesting authorization to construct and operate a new compression facility, with appurtenances, located in Converse County, Wyoming (Medicine Bow Expansion Project). Specifically, these facilities will be comprised of one natural gas driven compressor unit, with appurtenances, designed to transport up to 330,000 Dth per day on WIC's Medicine Bow Lateral system. As part of this project, WIC is also seeking a pre-determination of roll-in for the costs associated with this project and the related fuel costs from the proposed facilities, all as more fully set forth in the application on file with the Commission and open to public inspection. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, call (202) 502–8659 or TTY, (202) 208–3676.

Any questions regarding this application should be directed to Richard Derryberry, Director, Regulatory Affairs, Wyoming Interstate Company, Ltd., P.O. Box 1087, Colorado Springs, Colorado, 80944 at (719) 520–3788 or by fax at (719) 667–7534 or Craig V. Richardson, Vice President and General Counsel, Wyoming Interstate Company, Ltd.; P.O. Box 1087, Colorado Springs, Colorado, 80944 at (719) 520–4829 or by fax at (719) 520–4898.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties.

However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on July 6, 2007.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12184 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11910–002 Oregon]

Applegate Dam; Notice of Availability of Environmental Assessment

June 15, 2007.

In accordance with the National Environmental Policy Act of 1969 and Federal Energy Regulatory Commission (Commission) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), Office of Energy Projects staff have reviewed Symbiotics, LLC's application for the proposed Applegate Dam Project and prepared this environmental assessment (EA). The proposed project would be located at the existing U.S. Army Corps of Engineers' (Corps) Applegate dam located at river mile 45.7 on the Applegate River, near the town of Medford, in Jackson County, Oregon. The proposed project facilities would occupy 7.1 acres of federal land administered by the Corps below and adjacent to the dam. In addition, the project boundary would include 2.32 acres of National Forest System land and 0.66 acre of U.S. Bureau of Land Management land.

This EA contains the Commission staff's analysis of the potential future environmental effects of the project. Staff has concluded that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice and should be addressed to Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please affix ''Applegate Dam Project No. 11910–002'' to all comments. Comments may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-filing'' link.

Please contact Tim Looney by telephone at (202) 502–6096 or by e-mail at *Timothy.Looney@ferc.gov* if you have any questions.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12191 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. P–9988–015]

Augusta Canal Authority; Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, and Establishing Procedural Schedule for Relicensing and Deadline for Submission of Final Amendments

June 15, 2007.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New major license.

b. *Project No.:* P–9988–015.

c. *Date Filed:* May 31, 2007.

d. *Applicant:* Augusta Canal Authority.

e. *Name of Project:* King Mill Hydroelectric Project.

f. *Location:* The King Mill Project is located on the Augusta Canal about 6 miles downstream of the Augusta Diversion Dam, adjacent to the Savannah River, Richmond County, Augusta, GA. The project does not affect federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Mr. Dayton Sherrouse, Executive Director, Augusta Canal Authority, 1450 Green Street, Suite 400, Augusta, GA 30901; Telephone (706) 823–0440, Ext. 1.

i. *FERC Contact:* Sarah Florentino, Telephone (202) 502–6863, or e-mail *sarah.florentino@ferc.gov.* Additional information on Federal Energy Regulatory Commission (FERC) hydroelectric projects is available on FERC's Web site: *http://www.ferc.gov/industries/hydropower.asp.*

j. This application is not ready for environmental analysis at this time.

k. *Cooperating agencies:* We are asking Federal, State, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing such requests described in item m below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

l. Pursuant to Section 4.32(b)(7) of 18 CFR of the Commission's regulations, if

any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

m. *Deadline for filing additional study requests and requests for cooperating agency status:* July 30, 2007.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Additional study requests and requests for cooperating agency status may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

n. *Project Description:* The existing King Mill Hydroelectric Project consists of: (1) Intake works consisting of a 50-foot-long, 15-foot-high headgate and intake structure; (2) primary and secondary steel trash racks; (3) a 200-foot-long, 40-foot-wide, concrete-lined, open flume head race; (4) a 435-foot-long, 30-foot-wide brick and masonry powerhouse; (5) two vertical shaft turbine/generator units with an installed capacity of 2.25 megawatts; (6) a 435-foot-long, 30-foot-wide, concrete-lined, open tailrace section which returns flows to the Augusta Canal, and (7) appurtenant facilities. There is no dam or impoundment, as approximately 881 cfs of water is withdrawn from the Augusta Canal when operating at full capacity. Developed head is approximately 32 feet. The estimated generation is 14,366 MWh annually. Nearly all generated power is utilized by the Standard Textile Plant, located within the King Mill building, for textile production. No new facilities or changes in project operation are proposed.

o. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

p. You may also register online at *http://www.ferc.gov/esubscribenow.htm* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

q. With this notice, we are initiating consultation with the Georgia State Historic Preservation Officer (SHPO), as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36, CFR, at § 800.4.

r. *Procedural Schedule:* The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Issue Scoping Document 1 for comments	September 2007.
Request Additional Information (if necessary)	November 2007.
Notice of Acceptance/Notice of Ready for Environmental Analysis	February 2008.
Filing of interventions, recommendations, preliminary terms and conditions, and fishway prescriptions	April 2008.
Reply comments due	May 2008.
FERC issues single EA (without a draft)	September 2008.
Comments on EA due	November 2008.

s. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12188 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2835–026]

New York State Electric and Gas Corporation; Notice of Compliance Filing and Soliciting Comments, Motions To Intervene, and Protests

June 15, 2007.

Take notice that the following report has been filed with the Commission and is available for public inspection:

a. *Filing Type:* Whitewater Access Plan.

b. *Project No:* 2835–026.

c. *Date Filed:* May 23, 2007.

d. *Applicant:* New York State Electric and Gas Corporation (NYSEG).

e. *Name of Project:* Rainbow Falls Hydroelectric Project.

f. *Location:* On the Ausable River, in Clinton County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Hugh Ives, 89 East Avenue, Rochester, NY 14649. Phone: (585) 724–8209.

i. *FERC Contact:* Any questions on this notice should be addressed to Gina Krump at (202) 502–6704 or *gina.krump@ferc.gov*.

j. *Deadline for filing comments and /or motions:* July 6, 2007.

All documents (original and eight copies) should be filed with: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please include the project number (2835–026) on any comments or motions filed.

k. *Description of Proposal:* NYSEG filed a Whitewater Access Plan (plan) pursuant to article 414 of the project license. The plan addresses impacts of whitewater access and public usage on the upper Chasm boating on other recreational users of Ausable Chasm and Ausable River downstream. It includes an estimate of potential demand for whitewater boating, costs estimates for providing and maintaining access to the upper Chasm, and a proposal to possibly limit, continue, or discontinue whitewater access at the project. The plan recommends that whitewater access be discontinued at the site due to low usage, and safety and security concerns.

l. *Locations of the Application:* This filing is available for review and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371.

This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or call toll-free 1–866–208–3676, or for TTY, contact (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

n. *Filing and Service of Responsive Documents:* Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

o. *Agency Comments:* Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

p. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12189 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP07–310–000]

Mojave Pipeline Company; Notice of Informal Settlement Conference

June 18, 2007.

Take notice that an informal settlement conference will be convened in this proceeding commencing at 10 a.m. on June 27, 2007, at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the above-referenced dockets.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

FERC conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–1659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

For additional information, please contact Hollis Alpert at *hollis.alpert@ferc.gov* (202) 502–8783.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12179 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD07–12–000]

Reliability Standard Compliance and Enforcement in Regions With Independent System Operators and Regional Transmission Organizations; Notice of Technical Conference

June 15, 2007.

The staff of the Federal Energy Regulatory Commission will hold a technical conference in the above-referenced proceeding on September 18, 2007, at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC. It will be held in the Commission Meeting Room (Room 2C) starting at 9:30 a.m. ET. The conference will explore issues associated with cost recovery of penalties for Reliability Standard violations assessed against Independent System Operators and Regional Transmission Organizations, as set forth in Midwest Independent Transmission System Operator, Inc., 119 FERC ¶ 61,222 (May 31, 2007) in Docket Nos. ER07–701–000 and AD07–12–000.

This notice is to alert you to the date of the conference. Further notices will define the issues to be explored in greater detail. The conference will be transcribed and Web cast. All interested parties are invited, and there is no registration fee to attend.

Questions about the conference should be directed to Don Lekang by e-mail at *donald.lekang@ferc.gov* or by phone at 202–502–8127.

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12183 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM93–11–000]

Revisions to Oil Pipeline Regulations Pursuant to the Energy Policy Act of 1992; Notice of Annual Change in the Producer Price Index for Finished Goods

May 16, 2007.

The Commission's regulations include a methodology for oil pipelines to change their rates through use of an index system that establishes ceiling levels for such rates. The Commission bases the index system, found at 18 CFR 342.3, on the annual change in the Producer Price Index for Finished Goods (PPI–FG), plus one point three percent (PPI+1.3). The Commission determined in an ''Order Establishing Index For Oil Price Change Ceiling Levels'' issued March 21, 2006, that PPI+1.3 is the appropriate oil pricing index factor for pipelines to use.[1]

The regulations provide that the Commission will publish annually, an index figure reflecting the final change in the PPI–FG, after the Bureau of Labor Statistics publishes the final PPI–FG in May of each calendar year. The annual average PPI–FG index figures were 155.7 for 2005 and 160.4 for 2006.[2]

[1] 114 FERC ¶ 61,293 at P 2 (2006).

[2] Bureau of Labor Statistics (BLS) publishes the final figure in mid-May of each year. This figure is publicly available from the Division of Industrial Prices and Price Indexes of the BLS, at (202) 691–7705, and in print in August in Table 1 of the annual data supplement to the BLS publication

Thus, the percent change (expressed as a decimal) in the annual average PPI–FG from 2006 to 2007, plus 1.3 percent, is positive .043186.[3] Oil pipelines must multiply their July 1, 2006, through June 30, 2007, index ceiling levels by positive 1.043186 [4] to compute their index ceiling levels for July 1, 2007, through June 30, 2008, in accordance with 18 CFR 342.3(d). For guidance in calculating the ceiling levels for each 12 month period beginning January 1, l995,[5] *see Explorer Pipeline Company,* 71 FERC 61,416 at n.6 (1995).

In addition to publishing the full text of this Notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print this Notice via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426. The full text of this Notice is available on FERC's Home Page at the eLibrary link. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field and follow other directions on the search page.

User assistance is available for eLibrary and other aspects of FERC's Web site during normal business hours. For assistance, please contact the Commission's Online Support at 1–866–208–3676 (toll free) or 202–502–6652 (e-mail at *FERCOnlineSupport@ferc.gov*), or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. E-mail the Public Reference Room at *public.referenceroom@ferc.gov.*

Kimberly D. Bose,

Secretary.

[FR Doc. E7–12192 Filed 6–22–07; 8:45 am]

BILLING CODE 6717–01–P

Producer Price Indexes via the Internet at *http://www.bls.gov/ppi*]. To obtain the BLS data, click on ''Get Detailed PPI Statistics,'' and then under the heading ''Most Requested Statistics'' click on ''Commodity Data.'' At the next screen, under the heading ''Producer Price Index—Commodity,'' select the first box, ''Finished goods—WPUSOP3000'', then scroll all the way to the bottom of this screen and click on Retrieve data.

[3] [160.4 − 155.7] / 155.7 = 0.030186 + .013 = 0.043186.

[4] 1 + 0.043186 = 1.043186.

[5] For a listing of all prior multipliers issued by the Commission, see the Commission's website, *http://www.ferc.gov.* The table of multipliers can be found under the headings ''Oil'' and ''Index''.

DEPARTMENT OF ENERGY

Western Area Power Administration

Post-2009 Resource Pool, Loveland Area Projects

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of request for letters of interest.

SUMMARY: The Western Area Power Administration (Western), Rocky Mountain Region, a Federal power marketing agency of the Department of Energy (DOE), is publishing this notice of Request for Letters of Interest to determine which eligible new customers may be interested in an allocation of Federal power, and to gather information and comments to aid Western in determining the appropriate purposes for a proposed Loveland Area Projects (LAP) resource pool. Under the Energy Planning and Management Program (Program), a Federal power resource pool of up to 1 percent (not to exceed 7 megawatts) of the LAP's long-term marketable resource may become available October 1, 2009, within the LAP marketing area. This **Federal Register** notice initiates the process for the proposed resource pool.

DATES: Western will hold one public information forum on July 23, 2007, at 1:30 p.m. MDT.

ADDRESSES: The public information forum will be held at the Radisson Stapleton Plaza, 3333 Quebec Street, Denver, Colorado.

Send Letters of Interest to Mr. James D. Keselburg, Regional Manager, Rocky Mountain Region, Western Area Power Administration, 5555 East Crossroads Boulevard, Loveland, CO 80538–8986, or e-mail *POST2009LAP@wapa.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Melanie Reed, Contracts and Energy Services Manager, Rocky Mountain Region, Western Area Power Administration, 5555 East Crossroads Boulevard, Loveland, CO 80538–8986, telephone (970) 461–7229, e-mail *mreed@wapa.gov.*

SUPPLEMENTARY INFORMATION: On October 20, 1995, Western published the Final Program Rule at 60 FR 54151. The Final Rule became effective on November 20, 1995. Subpart C-Power Marketing Initiative of the Program, 10 CFR part 905, provides for project-specific resource pools and allocations of power from these pools to eligible new customers and/or for other appropriate purposes as determined by Western. The goal of the Program is to require planning for efficient electric energy use by Western's long-term firm power customers. Specifically, 10 CFR part 905.32 (b) provides:

> At two 5-year intervals after the effective date of the extension to existing customers, Western shall create a project-specific resource pool increment of up to an additional 1 percent of the long-term marketable resource under contract at the time. The size of the additional resource pool increment shall be determined by Western based on consideration of the actual fair-share needs of eligible new customers and other appropriate purposes.

Letters of Interest for the proposed LAP resource pool should contain the following information: Name(s) of the interested entity, entity's interest, geographic location of the entity, and suggested appropriate purposes of the resource pool. Letters of Interest will aid Western in determining potential eligible new customers as well as the appropriate purposes for the proposed resource pool. All Letters of Interest must be received by 4 p.m., MDT, on August 20, 2007. Letters of Interest submitted via regular mail through the United States Postal Service will be accepted if postmarked at least 3 days before August 20, 2007, and received no later than August 24, 2007. Western reserves the right to not consider any Letters of Interest that are received after the prescribed dates. Western does not consider that a Letter of Interest is an application for power from the proposed LAP Resource Pool. If Western decides to create the resource pool, it will publish a separate **Federal Register** notice seeking applications.

Availability of Information

All documents developed or retained by Western in developing this Post-2009 Resource Pool will be available for inspection and copying at the Rocky Mountain Regional office in Loveland, Colorado. Letters of Interest will be available for viewing at *http://www.wapa.gov/rm/PMcontractRM/Post2009.html* after the close of the submittal period.

Resource Pool Procedure Requirements

Determination Under Executive Order 12866

Western has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Environmental Compliance

Western completed an environmental impact statement on the Program, pursuant to the National Environmental Policy Act of 1969 (NEPA). The Record of Decision was published in the

Federal Register on October 12, 1995 (60 FR 53181). Western will comply with any additional NEPA requirements for this resource pool.

Dated: June 14, 2007.

Timothy J. Meeks,

Administrator.

[FR Doc. E7–12218 Filed 6–22–07; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Post-2010 Resource Pool, Pick-Sloan Missouri Basin Program—Eastern Division

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of request for letters of interest.

SUMMARY: The Western Area Power Administration (Western), Upper Great Plains Region, a Federal power marketing agency of the Department of Energy (DOE), is publishing this notice of Request for Letters of Interest from entities interested in an allocation of Federal power, to gather information to aid Western in determining the appropriate purposes for this proposed resource pool, and/or to provide comments regarding a proposed resource pool. A Federal power resource pool increment of up to 1 percent of the long-term marketable resource of the Pick-Sloan Missouri Basin Program—Eastern Division (P–SMBP—ED), up to approximately 20 megawatts, may become available January 1, 2011, under the Energy Planning and Management Program (Program). This **Federal Register** notice initiates the process for the proposed resource pool.

DATES: Western will hold one public information forum, on July 24, 2007, at 1:30 p.m. CDT.

ADDRESSES: Send Letters of Interest to Mr. Robert J. Harris, Regional Manager, Upper Great Plains Region, Western Area Power Administration, 2900 4th Avenue North, Billings, MT 59101–1266, or e-mail *ugppost2010@wapa.gov*. The public information forum will be held at the Holiday Inn, 100 West 8th Street, Sioux Falls, South Dakota.

FOR FURTHER INFORMATION CONTACT: Mr. John A. Pankratz, Public Utilities Specialist, Upper Great Plains Region, Western Area Power Administration, 2900 4th Avenue North, Billings, MT 59101–1266, telephone (406) 247–7392, e-mail *pankratz@wapa.gov*.

SUPPLEMENTARY INFORMATION: On October 20, 1995, Western published the Final Program Rule. The Final Rule became effective on November 20, 1995. Subpart C-Power Marketing Initiative of the Program, Final Rule, 10 CFR part 905, published at 60 FR 54151, provides for project-specific resource pools and allocations of power from these pools to eligible new customers and/or for other appropriate purposes as determined by Western. The goal of the Program is to require planning for efficient electric energy use by Western's long-term firm power customers. Specifically, 10 CFR part 905.32(b) provides:

> At two 5-year intervals after the effective date of the extension to existing customers, Western shall create a project-specific resource pool increment of up to 1 percent of the long-term marketable resource under contract at the time. The size of the additional resource pool increment shall be determined by Western based on consideration of the actual fair-share needs of eligible new customers and other appropriate purposes.

Letters of Interest for the proposed P–SMBP—ED resource pool should contain the following information: Name(s) of the interested entity, entity's interest, geographic location of the entity, and suggested appropriate purposes of the resource pool. Letters of Interest will aid Western in determining potential eligible new customers and/or the appropriate purposes for the proposed resource pool. All Letters of Interest must be received by 4 p.m., MDT, on August 20, 2007. Letters of Interest submitted via regular mail through the United States Postal Service will be accepted if postmarked at least 3 days before August 20, 2007, and received no later than August 24, 2007. Western reserves the right to not consider any Letters of Interest that are received after the prescribed dates. Western does not consider Letters of Interest as a means for application to this resource pool. Calls for application, if determined to be necessary, will be made in a subsequent notice published in the **Federal Register**.

Availability of Information

All documents developed or retained by Western in developing this Post-2010 Resource Pool will be available for inspection and copying at the Upper Great Plains Regional office in Billings, Montana. Letters of Interest will be available for viewing at *http://www.wapa.gov/ugp/Post2010/default.htm* after the close of the submittal period.

Resource Pool Procedure Requirements

Determination Under Executive Order 12866

Western has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Environmental Compliance

Western completed an environmental impact statement on the Program, pursuant to the National Environmental Policy Act of 1969 (NEPA). The Record of Decision was published in the **Federal Register** on October 12, 1995 (60 FR 53181). Western will comply with any additional NEPA requirements for this resource pool.

Dated: May 30, 2007.

Timothy J. Meeks,

Administrator.

[FR Doc. E7–12219 Filed 6–22–07; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Office of Management and Budget's (OMB) responses to Agency Clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Susan Auby (202) 566–1672, or e-mail at *auby.susan@epa.gov* and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

Omb Approvals

EPA ICR No. 1591.23; Regulation of Fuel and Fuel Additives: Gasoline Benzene Program (Final Rule); was approved 06/06/2007; OMB Number 2060–0277; expires 10/31/2007.

EPA ICR No. 1716.06; NESHAP for Wood Furniture Manufacturing Operations (Renewal); in 40 CFR part

63, subpart JJ; was approved 06/07/2007; OMB Number 2060–0324; expires 06/30/2010.

EPA ICR No. 1790.04; NESHAP—Phosphoric Acid Manufacturing and Phosphate Fertilizers Production (Renewal); in 40 CFR part 63, subparts AA and BB; was approved 06/07/2007; OMB Number 2060–0361; expires 06/30/2010.

EPA ICR No. 1799.04; NESHAP for Mineral Wool Production (Renewal); in 40 CFR part 63, subpart DDD; was approved 06/07/2007; OMB Number 2060–0362; expires 06/30/2010.

EPA ICR No. 1678.06; NESHAP for Magnetic Tape Manufacturing Operations (Renewal); in 40 CFR part 63, subpart EE; was approved 06/07/2007; OMB Number 2060–0326; expires 06/30/2010.

EPA ICR No. 2213.02; Information Collection Requirements for the Control of Evaporative Emissions from New and In-Use Portable Gasoline Containers (Final Rule); was approved 06/06/07; OMB Number 2060–0597; expires 06/30/2010.

EPA ICR No. 1765.04; Reporting and Recordkeeping Requirements for National Volatile Organic Compound Emission Standards for Automobile Refinish Coatings (Renewal); in 40 CFR part 59, subpart B; was approved 06/05/2007; OMB Number 2060–0353; expires 06/30/2010.

EPA ICR No. 1927.04; Reporting and Recordkeeping Requirements for the Emission Guidelines for Existing Commercial and Industrial Solid Waste Incineration (CISWI) Units (Renewal); in 40 CFR part 60, subpart DDDD; OMB Control Number 2060–0451; expires 06/30/2010.

EPA ICR No. 0877.09; RadNet (Renewal); was approved 05/22/2007; OMB Number 2060–0015; expires 05/31/2010.

EPA ICR No. 1926.04; NSPS for Commercial and Industrial Solid Waste Incineration Units (Renewal); in 40 CFR part 60, subpart CCCC; was approved 05/22/2007; OMB Number 2060–0450; expires 05/31/2010.

EPA ICR No. 1160.08; NSPS—Wood Fiberglass Insulation Manufacturing Plants, NESHAP–MACT–Wool Fiberglass Manufacturing Plants (Renewal); in 40 CFR part 60, subpart PPP and 40 CFR part 63, subpart NNN; was approved 05/23/2007; OMB Number 2060–0114; expires 05/31/2010.

EPA ICR No. 2243.01; Procedures for Implementing NEPA; in 40 CFR 6.506, 6.604, 6,703, and 6.803; was approved 05/21/2007; OMB Number 2020–0033; expires 09/30/2007.

EPA ICR No. 1797.04; NSPS for Standards of Performance for Storage Vessels for Petroleum Liquids for which Construction, Reconstruction, or Modification Commenced after June 11, 1973, and prior to May 19, 1978 (Renewal); in 40 CFR part 60, subpart K; was approved 05/21/2007; OMB Number 2060–0442; expires 05/31/2010.

EPA ICR No. 1056.09; New Source Performance Standards for Nitric Acid Plants (Renewal); in 40 CFR part 60, subpart G; was approved 05/21/2007; OMB Number 2060–0019; expires 05/31/2010.

EPA ICR No. 2096.03; NESHAP for Iron and Steel Foundries (Renewal); in 40 CFR part 63, subpart EEEEE; was approved 05/18/2007; OMB Number 2060–0543; expires 05/31/2010.

EPA ICR No. 2248.02; Applicant Background Questionnaire: Race, National Origin, Gender and Disability Demographics; in 29 CFR 1614.601; was approved 05/14/2007; OMB Number 2030–0045; expires 11/30/2007.

EPA ICR No. 1072.08; NSPS for Lead-Acid Battery Manufacturing; in 40 CFR part 60, subpart KK (Renewal); was approved 06/08/2007; OMB Number 2060–0081; expires 06/30/2010.

Comment Filed

EPA ICR No. 1189.19; Revisions to the RCRA Definition of Solid Waste (Proposed Rule); OMB Number 2050–0053; OMB filed comment on 05/25/2007.

EPA ICR No. 1693.04; Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting (Proposed Rule Related Addendum); in 40 CFR part 174; OMB filed comment on 05/21/2007.

Dated: June 18, 2007.

Sara Hisel-McCoy,

Acting Director, Collection Strategies Division.

[FR Doc. E7–12233 Filed 6–22–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2007–0484; FRL–8330–2]

Board of Scientific Counselors, National Center for Environmental Research (NCER) Standing Subcommittee Meeting—2007

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Public Law 92–463, the Environmental Protection Agency, Office of Research and Development (ORD), gives notice of a meeting of the Board of Scientific Counselors (BOSC) National Center for Environmental Research (NCER) Standing Subcommittee.

DATES: The meeting (a teleconference call) will be held on Friday, July 13, 2007 from 10 a.m. to 12 p.m All times noted are eastern time. The meeting may adjourn early if all business is finished. Requests for the draft agenda or for making oral presentations at the conference call will be accepted up to 1 business day before the meeting.

ADDRESSES: Participation in the meeting will be by teleconference only—meeting rooms will not be used. Members of the public may obtain the call-in number and access code for the call from Susan Peterson, whose contact information is listed under the **FOR FURTHER INFORMATION CONTACT** section of this notice. Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2007–0484, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail:* Send comments by electronic mail (e-mail) to: ORD.Docket@epa.gov, Attention Docket ID No. EPA–HQ–ORD–2007–0484.
- *Fax:* Fax comments to: (202) 566–0224, Attention Docket ID No. EPA–HQ–ORD–2007–0484.
- *Mail:* Send comments by mail to: Board of Scientific Counselors, National Center for Environmental Research (NCER) Standing Subcommittee—2007 Docket, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. EPA–HQ–ORD–2007–0484.
- *Hand Delivery or Courier.* Deliver comments to: EPA Docket Center (EPA/DC), Room B102, EPA West Building, 1301 Constitution Avenue, NW., Washington, DC, Attention Docket ID No. EPA–HQ–ORD–2007–0484. **Note:** this is not a mailing address. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2007–0484. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise

protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Board of Scientific Counselors, National Center for Environmental Research (NCER) Standing Subcommittee—2007 Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the ORD Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer via mail at: Susan Peterson, Mail Code 8104-R, Office of Science Policy, Office of Research and Development, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via phone/voice mail at: (202) 564–1077; via fax at: (202) 565–2911; or via e-mail at: *peterson.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

Participation in the meeting will be by teleconference only—meeting rooms will not be used. Members of the public who wish to obtain the call-in number and access code to participate in the conference call may contact Susan Peterson, the Designated Federal Officer, via any of the contact methods listed in the ''**FOR FURTHER INFORMATION CONTACT**'' section above, by 4 working days prior to the conference call.

The purpose of the meeting is to provide the subcommittee with background information on the Office of Research and Development (ORD) and one of ORD's Centers, the National Center for Environmental Research (NCER). Proposed agenda items for the conference call include, but are not limited to: Overview of subcommittee objectives, overview of ORD, overview of NCER, and discussion of the charge to subcommittee. The conference call is open to the public.

Information on Services for Individuals with Disabilities: For information on access or services for individuals with disabilities, please contact Susan Peterson at (202) 564–1077 or *peterson.susan@epa.gov.* To request accommodation of a disability, please contact Susan Peterson, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Dated: June 14, 2007.

Maryellen Radzikowski,

Acting Director, Office of Science Policy.

[FR Doc. E7–12230 Filed 6–22–07; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Economic Impact Policy

This notice is to inform the public that the Export-Import Bank of the United States has received an application to guarantee approximately $20 million in commercial bank financing for the export of approximately $28.9 million of U.S. equipment, including a plasma cold hearth melting system, an electron beam cold hearth melting furnace and a plasma welding unit to a titanium ingot producer in China. The equipment will be used to generate an additional 4,500 metric tons of titanium ingot. Available information indicates that this new production will be consumed 100% in China. Interested parties may submit comments on this transaction by e-mail to *economic.impact@exim.gov* or by mail to 811 Vermont Avenue, NW., Room 1238, Washington, DC 20571, within 14 days of the date this notice appears in the **Federal Register**.

Helene S. Walsh,

Director, Policy Oversight and Review.

[FR Doc. E7–12236 Filed 6–22–07; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

PREVIOUSLY SCHEDULED DATE AND TIME: Tuesday, June 26, 2007, Meeting closed to the public. This meeting has been rescheduled to Thursday, June 28, 2007, to begin at the conclusion of the open meeting.

DATE AND TIME: Thursday, June 28, 2007 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Future Meeting Dates.

Management and Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Robert Biersack, Press Officer, Telephone (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 07–3127 Filed 6–21–07; 2:18 pm]

BILLING CODE 6715–01–M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

The Following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney

General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

Trans No.	Acquiring	Acquired	Entities
TRANSACTIONS GRANTED EARLY TERMINATION—04/17/2007			
20071039	The Coca-Cola Company	Nestle S.A	Nestle USA, Inc.
20071040	Fursa Alternative Strategies LLC	ASM International N.V	ASM International N.V.
20071067	Huntington Bancshares Incorporated	Sky Financial Group, Inc	Sky Financial Group, Inc.
20071068	Citadel Broadcasting Corporation	ABC Radio Holdings, Inc., c/o The Walt Disney Company.	ABC Radio Holdings, Inc., c/o The Walt Disney Company.
20071071	KarstadtQuelle AG	MyTravel Group plc	MyTravel Group plc.
20071073	CDRSVM Topco, Inc	The ServiceMaster Company	The ServiceMaster Company.
20071074	Bank of Montreal	World Class Strategy I, L.P	World Class Strategy I, L.P.
20071077	Court Square Capital Partners II, L.P	Newmarket International, Inc	Newmarket International, Inc.
20071079	Blackstone Capital Partners V USS L.P	William J. Nicholson Agreement of Trust Dated 12/30/1076.	RGIS Holdings, LLC.
20071080	PXRE Group Ltd	Argonaut Group, Inc	Argonaut Group, Inc.
20071081	EQT V (UK No. 1) LP	Dako A/S	Dako Denmark A/S.
20071082	Hellerman & Friedman Captial Partners VI, L.P.	Kronos Incorporated	Kronos Incorporated.
20071084	Cinram International Income Fund	Ditan Corporation	Ditan Corporation.
20071086	Koninklijke Philips Electronics N.V	Jeffrey L. Grady	Netalog, Inc.
20071095	Deutsche Bank AG	Hayes Lemmerz International, Inc	Hayes Lemmerz International, Inc.
20071096	James A.C. Kennedy	T. Rowe Price Associates, Inc	T. Rowe Price Associates, Inc.
20071100	Silver Point Capital Offshore Fund, Ltd	Hayes Lemmerz International, Inc	Hayes Lemmerz International, Inc.
20071104	Silver Point Capital Fund, L.P	Hayes Lemmerz International, Inc	Hayes Lemmerz International, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—04/18/2007			
20071094	Ad.Venture Partners, Inc	180 Connect Inc	180 Connect Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—04/19/2007			
20071043	Kenwood Corporation	Milton Zeutschel	Zetron Holdings, Inc.
20071047	Dennis Mehiel	Longview Fibre Company	Longview Fibre Paper and Packaging, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—04/20/2007			
20071078	Avery Dennison Corporation	Paxar Corporation	Paxar Corporation.
20071087	CHS Inc	M&M Cooperative, Inc	M&M Cooperative, Inc.
20071106	Comcast Corporation	Fandango, Inc	Fandango, Inc.
20071110	Copano Energy, L.L.C	Taos Gathering, L.P	Cimmarron Gathering, L.P. Cimmarron Gathering, L.P. HEP Oil Company Ltd.
20071111	Copano Energy, L.L.C	HEP Oil Company, Ltd	Cimmarron Gathering, LP.
20071116	Dr. Phillip Frost	Continucare Corporation	Continucare Corporation.
20071117	VSS-AHC Holdings LLC	DLJ Merchant Banking Partners III, L.P	Advanstar Holdings Corp.
20071121	ESP Energias de Portugal, S.A	The Goldman Sachs Group, Inc	Horizon Wind Energy Company LLC. Horizon Wind Energy LLC.
20071123	Farmers Insurance Exchange	Zurich Financial Services	Bristol West Holdings, Inc.
20071126	HOLD CyC	Atradius, N.V	Atradius, N.V.
20071127	Sam Investment Trust	Tribune Company	Tribune Company.
20071128	GGC Investments II (BVI), L.P	Workbrain Corporation	Workbrain Corporation.
20071133	George J. Pedersen, c/o ManTech International Corporation.	Mohindar S. Sandhu	SRS Technologies, Inc.
20071136	AT&T Inc	Council Tree Alaska Native Wireless, L.L.C.	Alaska Native Wireless, L.L.C.
TRANSACTIONS GRANTED EARLY TERMINATION—04/23/2007			
20071064	Ampac Packaging, LLC	Mohawk Northern Plastics, Inc	Mohawk Northern Plastics, Inc.
20071070	Silver Lake Partners II, L.P	J.P. Morgan Chase & Co	Westcom Holding Corp.
20071076	BG Group plc	Silver Point Capital Offshore Fund, Ltd	Silver Ship Offshore II, Inc. Silver Ship Offshore I, Inc.
20071124	Nippon Oil Corporation	Anadarko Petroleum Corporation	Anadarko Petroleum Corporation.
20071125	Mitsubishi Corporation	Anadarko Petroleum Corporation	Anadarko Petroleum Corporation.
TRANSACTIONS GRANTED EARLY TERMINATION—04/25/2007			
20071090	Schering-Plough Corporation	AVEO Pharmaceuticals, Inc	AVEO Pharmaceuticals, Inc.
20071130	TPG Partners V, L.P	HealthSouth Corporation	Surgery Holdings, LLC.

Trans No.	Acquiring	Acquired	Entities
20071132	Audax Private Equity Fund II, L.P	UTEX Holding, Inc	UTEX Holding, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—04/27/2007			
20071075	West Corporation	Douglas R. and Elaine M. Wilwerding, husband and wife.	Omnium Worldwide, Inc.
20071088	Iron Mountain Incorporated	Housatonic Equity Investors, L.P	ArchivesOne, Inc.
20071089	Iron Mountain Incorporated	Adam J. Wasserstein	ArchivesOne, Inc.
20071113	Bruce M. Rose	New Century Financial Corporation	New Century Mortgage Corporation.
20071143	LGB Cap Rock LLC	SEMCO Energy, Inc	SEMCO Energy, Inc.
20071146	Range Resources Corporation	Nora Gathering, LLC	Nora Gathering, LLC.
20071147	The AES Corporation	General Electric Company	Lake Benton Power Partners LLC.
20071148	Caxton Global Investments Limited	KCP Income Fund	KIK Operating Trust.
20071152	AXIS Capital Holdings Limited	Aon Corporation	MPI Insurance Agency, Inc.
20071158	New Omaha Holdings, L.P	First Data Corporation	First Data Corporation.
20071159	Software AG	webMethods, Inc	webMethods, Inc.
20071161	Filtrona plc	Duraco, Inc	Duraco, Inc.
20071166	Olympus Growth Fund IV, L.P	Brinker International, Inc	Brinker Connecticut Corporation. Brinker Massachusetts Corporation. Brinker New England II, LLC. Brinker New England I, LLC. Brinker North Carolina, Inc. Brinker Restaurant Corporation. Brinker Rhode Island, Inc. Brinker South Carolina, Inc. Brinker Vermont, Inc. Brinker Virginia, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—04/30/2007			
20071105	Bayer AG	Novartis AG	Novartis Vaccines and Diagnostics, Inc.
20071134	Greenwood Tree Farm Fund, LP	Potlatch Corporation	Potlatch Forest Holdings, Inc. Potlatch Forest Products Corporation.
20071164	OCM Principal Opportunities Fund IV AIF (Delaware), L.P.	Clear Channel Communications, Inc	AMFM Radio Licenses, LLC. Capstar Radio Operating Company. Capstar TX Limited Partnership. CCB Texas Licenses, L.P. Citicasters Co. Citicasters Licenses LP. Clear Channel Broadcasting, Inc. Clear Channel Identity, LP.
20071165	Bear Stearns Merchant Banking Partners.	Universal Hospital Services, Inc	Universal Hospital Services, Inc.
20071168	Roark-Carvel LLC	H. Martin Sprock, III	Moe's Southwest Grill, LLC.
TRANSACTIONS GRANTED EARLY TERMINATION—05/01/2007			
20071169	Thoma Cressey Fund VIII, L.P	SvoCO, L.P	Midwest Dental Holding Company, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/02/2007			
20070507	Saskatchewan Wheat Pool, Inc	United Grain Growers Limited	United Grain Growers Limted.
20071093	NuVox, Inc	M/C Venture Partners V, L.P	Florida Digital Network, Inc.
20071153	Community Education Centers, Inc	CiviGenics, Inc	CiviGenics, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/03/2007			
20071162	First Data Corporation	Warburg, Pincus Equity Partners, L.P	FundsXpress, Inc.
20071167	Apollo Investment Fund VI, L.P	Xstrata plc	Noranda Aluminum Holding Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/04/2007			
20070036	Smithfield Foods, Inc	Premium Standard Farms, Inc	Premium Standard Farms, Inc.
20070577	R.R. Donnelley & Sons Company	Visant Holding Corp	Von Hoffmann Holdings, Inc.
20071196	L'Oreal S.A	TSG4 L.P	PR Holding Corp.
TRANSACTIONS GRANTED EARLY TERMINATION—05/07/2007			
20070037	ContiGroup Companies, Inc	Smithfield Foods, Inc	Smithfield Foods, Inc.
20071015	Quanta Services, Inc	InfraSource Services, Inc	InfraSource Services, Inc
20071172	Arthur L. Allen	Mobius Management Systems, Inc	Mobius Management Systems, Inc.
20071174	Newco	Hub International Limited	Hub International Limited.
20071177	Babcock & Brown Limited	New Energy Capital Corporation	Iroquois Bio-Energy Company, LLC.
20071180	New Wave Group AB	Cutter & Buck Inc	Cutter & Buck Inc.

Trans No.	Acquiring	Acquired	Entities
20071182	Fenway Partners Capital Fund III, L.P	Cesar Scolari	Staffworks Dedicated Logistics Services, LLC. Staffworks, Inc.
20071184	Joseph C Grendys	Don Tyson	Tyson Foods, Inc.
20071185	STR Holdings, Inc	Whitney STR Holdings, LLC	Specialized Technology Resources, Inc.
20071190	Boulder Specialty Brands, Inc	TSG4 L.P	GFA Holdings, Inc.
20071191	Hellman & Friedman Capital Partners VI, L.P.	Catalina Marketing Corporation	Catalina Marketing Corporation.
20071194	Great Hill Equity Partners III, LP	Smart Business Advisory and Consulting LLC.	Smart Business Advisory and Consulting, LLC.
20071195	OZ Overseas Fund, Ltd	Boulder Specialty Brands, Inc	Boulder Specialty Brands, Inc.
20071200	GTCR Fund IX/A, L.P	H.I.G. Capital Partners III, L.P	APS Healthcare, Inc. Service Net Holdings, Inc.
20071205	Olam International Limited	Universal Blanchers, L.L.C	Universal Blanchers, L.L.C.
20071206	Silver Oak Services Partners, L.P	CGW Southeast Partners III, L.P	Convergent Resources, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/09/2007			
20071151	Agilent Technologies, Inc	Stratagene Corporation	Stratagene Corporation.
20071181	BGH GP Holdings, LLC	Carlyle/Riverstone BPL Investment Partnership II, L.P.	Buckeye GP Holdings L.P.
TRANSACTIONS GRANTED EARLY TERMINATION—05/10/2007			
20071108	United States Steel Corporation	Lone Star Technologies, Inc	Lone Star Technologies, Inc.
20071173	Curtiss-Wright Corporation	John Brennan	Valve Systems and Controls, LP.
20071176	Citadel Wellington LLC	Lowell W. Paxson	ION Media Networks, Inc.
20071178	CVC European Equity Partners III, L.P	Greenwich Street Capital Partners, L.P	Day International Group, Inc.
20071183	Klockner & Co. AG	Primary Steel, LLC	Primary Steel, LLC.
20071187	Deutsche Bank AG	M. Brian Maher	Maher Prince Rupert Holdings Corp. Maher Terminals USA, LLC.
20071188	Deutsche Bank AG	Basil Maher	Maher Prince Rupert Holdings Corp. Maher Terminals USA, LLC.
20071193	Macquarie Infrastructure Company Trust.	Allied Capital Corporation	Mercury Air Centers Inc.
20071208	ITC Holdings Corp	Alliant Energy Corporation	Interstate Power and Light Company.
20071219	Bruno Bolfo	Winner Steel, Inc	Winner Steel, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/11/2007			
20071129	Lightyear Fund II, L.P	Odyssey Investment Partners Fund, LP	Neff Corp.
20071139	Carlyle Partners IV, L.P	The Goodyear Tire & Rubber Company.	Belt Concepts of America, Inc. Cosmoflex, Inc. Goodyear Engineered Products International, Inc. Specialty Fabrics and Converting, Inc.
20071170	O. Bruton Smith	David L. Peterson	Calabasas Motorcars, Inc.
20071198	UnitedHealth Group Incorporated	Quintiles Transnational Corp	The Lewin Group, Inc.
20071210	Blackstone Capital Partners (Cayman) IV L.P.	Kimble Chase Life Science and Research Products, LLC.	Kimble Chase Life Science and Research Products, LLC.
20071214	Challenger Infrastructure Fund	JP Morgan Chase & Co	LBC Holdings LLC.
20071215	Citigroup Inc	Old Lane Holdings, LP	Old Lane Partners GP, LLC. Old Lane Partners LP.
20071226	Liberty Media Corporation	Gaylord Entertainment Company	ResortQuest Real Estate of Hawaii, Inc. RQI Holdings, Ltd.
20071241	J.C. Flowers II L.P	Direct Response Corporation	Direct Response Corporation.
20071247	Bank of America Corporation	Seattle Financial Group, Inc	Seattle Mortgage Company. Seattle Savings Bank.
20071248	Information Services Group, Inc	MCP–TPI Holdings, LLC	c/o Technology Partners International, Inc. TPI Advisory Services Americas, Inc.
20071250	SCT Chassis Holding LLC	Interpool, Inc	Interpool, Inc.
20071259	A/S Dampskibsselskabet TORM	OMI Corporation	OMI Corporation.
20071260	Teekay Shipping Corporation	OMI Corporation	OMI Corporation.
20071264	Audax Private Equity Fund II, L.P	Thermon Industries, Inc	Thermon Industries, Inc.
20071275	TUI AG	First Choice Holidays PLC	First Choice Holidays PLC.
TRANSACTIONS GRANTED EARLY TERMINATION—05/14/2007			
20070898	CheckFree Corporation	Corillian Corporation	Corillian Corporation.
20071225	Barry Diller	Gaylord Entertainment Company	ResortQuest Real Estate of Hawaii, Inc.

Trans No.	Acquiring	Acquired	Entities
20071230	Carl C. Icahn	WCI Communities, Inc	WCI Communities, Inc.
20071233	Sun Capital Partners IV, L.P	Wellspring Capital Partners III, L.P	EWGS Partners. WS Golf Acquisition, Inc.
20071234	Sun Capital Partners V, L.P	Wellspring Capital Partners III, L.P	EWGS Partners. WS Golf Acquisition, Inc.
20071238	Vinci S.A	HIGB	Soletanche S.A.
20071239	Aquilex Holdings LLC	OCM Principal Opportunities Fund III, L.P.	HydroChem Holding, Inc.
20071246	MYEH Corporation	Myers Industries, Inc	Myers Industries, Inc.
20071249	Staples, Inc	James H. Possehl	American Identity, Inc. IN Designs Global, Inc. Legend, Inc.
20071256	TreeHouse Foods, Inc	Christopher ''Kit'' Goldsbury	c/o Silver Brands Partners II, L.P. VDW Acquisition, Ltd.
TRANSACTIONS GRANTED EARLY TERMINATION—05/15/2007			
20071258	Walgreen Co	Beecken Petty O'Keefe & Company	Take Care Health Systems, Inc.
20071261	DC Chemical Co., Ltd	Evergreen Solar, Inc	Evergreen Solar, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/16/2007			
20071163	Experian Group Limited	Hitwise, Inc	Hitwise, Inc.
20071201	Dubai Aerospace Enterprise (DAE) Ltd	Carlyle Partners III, L.P	Standard Aero Acquisition Holdings, Inc.
20071202	Dubai Aerospace Enterprise (DAE) Ltd	Carlyle Piedmont Domestic Partners, L.P.	Piedmont/Hawthorne Holdings, Inc.
20071262	Jubilant Organosys Ltd	Windward Capital Partners II LP	Hollister-Stier Laboratories LLC
20071263	Highstar Harbor Holdings II, Inc	Lincolnshire Equity Fund III, L.P	Logistics Acquisition Holdings, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/17/2007			
20070969	James Richardson & Sons Limited	United Grain Growers Limited d/b/a Agricore Limited.	United Grain Growers Limited d/b/a Agricore Limited.
TRANSACTIONS GRANTED EARLY TERMINATION—05/18/2007			
20071186	Oplink Communications, Inc	The Furukawa Electric Co., Ltd	Optical Communication Products, Inc.
20071251	O. Bruton Smith	Dennis Assael	Assael Automotive, Inc.
20071268	TA X, L.P	IntraLinks, Inc	IntraLinks, Inc.
20071270	Genstar Capital Partners IV, L.P	Nautic Partners V, L.P	ConvergeOne Holdings Corp.
20071279	Symbol Acquisition, L.L.C	Symbion, Inc	Symbion, Inc.
20071282	BBA Aviation PLC	Topeka Aircraft, Inc	Topeka Aircraft, Inc.
20071283	HBK Fund, L.P	Piedmont Television Holdings, LLC	Piedmont Television of Savannah LLC.
20071284	Citigroup Inc	Accor SA	Red Roof Inns, Inc.
20071285	Oak Hill Capital Partners II, L.P	Wells Fargo & Company	Jacobson Holding Co.
20071286	L–1 Identity Solutions, Inc	Frank White, Jr	Advanced Concepts, Inc.
20071288	Welsh, Carson, Anderson & Stowe X, L.P.	Carlyle Partners III Hawaii, L.P	Directory Co., LLC.
20071290	Coventry Health Care, Inc.	Mutual of Omaha Insurance Company	Mutual of Omaha Insurance Company.
20071291	CS Luxco s.a.r.l.	Capital Safety Group Limited	Capital Safety Group Limited.
20071292	KHI Holdings LP	Harman International Industries Incorporated.	Harman International Industries Incorporated.
20071306	Alleghany Corporation	Employers Direct Corporation	Employers Direct Corporation.
TRANSACTIONS GRANTED EARLY TERMINATION—05/21/2007			
20071217	Sciele Pharma, Inc	Alliant Pharmaceuticals, Inc	Alliant Pharmaceuticals, Inc.
20071245	RG Tube Holdings LLC	Castle Harlan Partners IV, L.P	RGCH Holdings Corp.
20071280	Kenneth A. Hendricks	William Davidson	Ashley Aluminum, LLC.
20071296	Welsh, Carson, Anderson & Stowe X, L.P.	GTCR Fund VII, L.P	TransFirst Holdings, Inc.
20071301	Hellman & Friedman Capital Partners VI, L.P.	J.W. Childs Equity Partners III, L.P	Sheridan Holdings, Inc.
20071305	Battery Ventures VII, L.P.	Quovadx, Inc	Quovadx, Inc.
20071310	Sorenson Capital Partners, LP	Mity Enterprises, Inc	Mity Enterprises, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/22/2007			
20071295	Visa Inc	Visa U.S.A. Inc	Visa U.S.A. Inc.
20071307	Visa Inc.	Visa International Service Association	Visa International Service Association.
20071308	Visa Inc	Visa Canada Association	Visa Canada Association.
20071309	MartlinPatterson Global Opportunities Partners II L.P.	World Air Holdings, Inc	World Air Holdings, Inc.
20071320	Genesis Energy, L.P	Davison Petroleum Products, LLC.	Fuel Masters, LLC.

Trans No.	Acquiring	Acquired	Entities
			TDC, LLC.
			T&T Chemical, Inc.
20071321	Genesis Energy, L.P	Davison Transport, Inc	Davison Transport, Inc.
20071327	Carlyle Partners III, L.P	TSS Holdings, Inc	TSS Aviation, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/23/2007			
20071220	The Crawford Group, Inc	Cerberus International, Ltd	Vanguard Car Rental Holdings LLC.
20071223	Blue Point Capital Partners II, L.P	Bruce Degler	Dispatch Transportation, LLC.
20071224	Blue Point Capital Partners II, L.P	Kim Pugmire	Dispatch Transportation, LLC.
20071271	Manulife Financial Corporation	J-Power USA Generation, L.P	J-Power USA Generation, L.P.
20071272	Estate of Craig H. Neilsen	Colony Investors VII, L.P	RIH Acquisitions IN, LLC.
20071276	Sonoco Products Company	Tricor Pacific Capital Partners (Fund III) Limited Partnership.	Matrix Packaging Inc.
			Tricor (Matrix) Holdings Ltd.
TRANSACTIONS GRANTED EARLY TERMINATION—05/24/2007			
20061865	Newhouse Broadcasting Corporation	Cequel Communications Holdings, LLC	Cebridge Acquisition, L.P.
20070606	Psychiatric Solutions, Inc	Horizon Health Corporation	Horizon Health Corporation.
20071189	Eltek ASA	Valere Power, Inc	Valere Power, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/25/2007			
20071236	JANA Offshore Partners, Ltd	LSI Logic Corporation	LSI Logic Corporation.
20071273	Quadrangle (AIV) Capital Partners II LP.	Hargray Communications Group, Inc	Hargray Communications Group, Inc.
20071319	TIBCO Software Inc	Spotfire Holdings, Inc	Spotfire Holdings, Inc.
20071323	Whitehall Street Global Real Estate Limited Partnership 2007.	Carl C. Icahn	American Casino & Entertainment Properties, LLC.
20071325	Deutsche Borse AG	International Securities Exchange Holdings, Inc.	International Securities Exchange Holdings, Inc.
20071333	Randal J. Kirk	Halozyme Therapeutics, Inc	Halozyme Therapeutics, Inc.
20071336	Trevor Lloyd	Quadrangle (Access) Capital Partners, L.P.	Global Energy Decisions, L.L.C.
20071339	Bunker Hill Capital, L.P	The Smith & Wollensky Restaurant Group, Inc.	The Smith & Wollensky Restaurant Group, Inc.
20071340	PRWireless LLC	ClearComm, LP	NewComm Wireless Services, Inc.
20071344	The PNC Financial Services Group, Inc.	L.E.G.L. Investments, LLC	ARCS Commercial Mortgage Co., L.P.
20071348	MidCountry Financial Corp	William D. Sullivan	Pioneer Financial Industries, Inc.
20071349	Madison Dearborn Capital Partners V–A, L.P.	Clayton, Dubilier & Rice Fund VI Limited Partnership.	CDRV Investors, Inc.
20071356	GGC Investments II (BVI), L.P	GGC Investment Fund II, L.P	Hansen Information Technologies Holdings, Inc.
20071357	American Capital Strategies, Ltd	SMG	SMG.
20071361	Water Street Healthcare Partners, L.P	Stryker Corporation	Physiotheraphy Associates, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—05/29/2007			
20071211	Highmark Inc	Independence Blue Cross	Independence Blue Cross.
20071213	Independence Blue Cross	Highmark, Inc	Highmark, Inc.
20071218	Hercules Offshore, Inc	TODCO	TODCO.
20071278	Michael E. Heisley, Sr	Jordan Reese, III	Bo-Mac Contractors, Ltd.
20071303	AstraZeneca plc	Medimmune, Inc	Medimmune, Inc.
20071331	Verizon Communications Inc	JPMorgan Chase & Co	Cybertrust Holdings, Inc.
20071345	Natural Gas Partners VIII, L.P	MDU Resources Group, Inc	Centennial Power, Inc.
			Colorado Energy Management, LLC.
20071358	Terra Firma Capital Partners II, LP–C	Pegasus Aviation Finance Company	Pegasus Aviation Finance Company.
20071359	Terra Firma Capital Partners III, L.P	Terra Firma Capital Partners II, LP–C	Carmel Capital S.A.R.L.
TRANSACTIONS GRANTED EARLY TERMINATION—05/30/2007			
20071299	IASIS Investment LLC	Alliance Hospital, Ltd	Alliance Hospital, Ltd.
20071372	Express Investment Corp	Limited Brands, Inc	Express Holding, LLC.
TRANSACTIONS GRANTED EARLY TERMINATION—05/31/2007			
20071300	SAP AG	OutlookSoft Corporation	OutlookSoft Corporation.
20071322	Linx Fund II, L.P	McBride Electric, Inc	McBride Electric, Inc.
20071330	Doughty Hanson & Co V	Norit International B.V	Norit Americas Inc.
			Sudmo North America, Inc.
20071338	Herbert C. Chambers	Foreign Motors West, Inc. Employee Stock Ownership Plan.	Bentley of Boston, LLC.
			Foreign Motors West, Inc.

Trans No.	Acquiring	Acquired	Entities
			Landrover MetroWest, LLC.
20071351	Barry Diller	Thomas H. Lee Equity Fund V, L.P	Front Line Management Group, Inc.
20071352	Liberty Media Corporation	Thomas H. Lee Equity Fund V, L.P	Front Line Management Group, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—06/01/2007			
20061806	Rite Aid Corporation	Mr. Jean Coutu	The Jean Coutu Group (PJC) USA, Inc.
20061807	Mr. Jean Coutu	Rite Aid Corporation	Rite Aid Corporation.
20071293	Novartis AG	Antisoma PLC	Antisoma Research Limited.
TRANSACTIONS GRANTED EARLY TERMINATION—06/04/2007			
20071122	Travelex Holdings Limited	Welsh, Carson, Anderson & Stowe IX, L.P.	RII Holdings, Inc., c/o Ruesch International Inc.
20071155	The Bank of New York Company, Inc	Mellon Financial Corporation	Mellon Financial Corporation.
20071156	Mellon Financial Corporation	The Bank of New York Company, Inc	The Bank of New York Company, Inc.
TRANSACTIONS GRANTED EARLY TERMINATION—06/05/2007			
20071360	Motorola, Inc	Terayon Communication Systems, Inc	Terayon Communication Systems, Inc.
20071365	UBS AG	AIG Highstar Generation LLC	AIG Highstar Generation LLC.
20071368	Imation Corp	Barry Smith	Hopper Radio of Florida, Inc.
			Memcorp, Asia Limited.
			Memcorp, Inc.
20071369	ASP IV Alternative Investments, L.P	Clear Channel Communications, Inc	AM/FM Radio Licenses, LLC.
			Capstar Radio Operating Company.
			Capstar TX Limited Partnership.
			CC Licenses, LLC.
			Citicasters Co.
			Citicasters Licenses LP.
			Clear Channel Broadcasting Inc.
			Clear Channel Broadcasting Licenses, Inc.
			Jacor Broadcasting Corp.
20071378	Torquest Partners Fund II, L.P	3M Company	3M Company.
			3M Innovative Properties Co.
20071380	Babcock & Brown Limited	Celanese Corporation	Celanese Corporation.
20071383	Lehman Brothers Holdings Inc	Eagle Energy Partners I, L.P	Eagle Energy Partners I, L.P.
20071385	Paul G. Desmarais	HARO Financial Corporation	Crown Life Insurance Company.
20071387	General Electric Company	Shady Hills Power Holdings, LLC	Shady Hills Power Holdings, LLC.
20071392	Exar Corporation	Sipex Corporation	Sipex Corporation.
20071396	TCV VI, L.P	Thomas A. Smith	Seismic Micro-Technology, Inc.
20071400	Ingram Micro Inc	David B. Lorsch	DBL Distributing, Inc.
20071404	Jeffrey D. Zients	Pediatric Services of America, Inc	Pediatric Services of America, Inc.
20071407	WGN Acquisition Corp	National Grid plc	National Grid Wireless LLC.
20071413	Aetna Inc	Schaller Anderson, Incorporated	Schaller Anderson, Incorporated.
20071416	Spectrum Equity Investors V, L.P	Fuji Television Network, Inc	T/Q Music, Inc.
			Windswept Holdings, LLC.
20071423	Fetcher Building Limited	Formica Bermuda Holdings, Ltd	Formica Holding Corp.
			Formica Luxembourg Holding S.ar.l.
			Laminates Acquisition Co.
20071428	Triarc Companies, Inc	Deerfield Triarc Capital Corp	Deerfield Triarc Capital Corp.
20071429	Deerfield Triarc Capital Corp	Triarc Companies, Inc	Deerfield & Company LLC.
TRANSACTIONS GRANTED EARLY TERMINATION—06/06/2007			
20070789	Walter Wang	PW Eagle, Inc	PW Eagle, Inc.
20071329	Lonestar Holdings Corp	Asurion Corporation	Asurion Corporation.
20071409	University of Miami	Hercules Holdings II, LLC	Cedarcare, Inc.
			Cedars Gastroenterologists, LLC.
			Cedars Healthcare Group, Ltd.
			Cedars Neurosurgery, LLC.
20071417	Pfizer Inc	PTC Therapeutics, Inc	PTC Therapeutics, Inc.
20071418	KKR Asian Fund, L.P	MMI Holdings Limited	MMI Holdings Limited.
20071419	Atlas America, Inc	DTE Energy Company	DTE Gas & Oil Company.
TRANSACTIONS GRANTED EARLY TERMINATION—06/07/2007			
20071314	Chicago Growth Partners, L.P	Industrial Growth Partners II, L.P	Jonathan Engineered Solutions Corp.
			Jonathan Manufacturing Corporation.
20071370	Boston Scientific Corporation	Celsion Corporation	Celsion Corporation.
20071411	Harris Corporation	Cerberus Partners, L.P	Multimax Incorporated.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative or Renee Hallman, Contact Representative Federal Trade Commission Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By direction of the Commission.

Donald S. Clark

Secretary.

[FR Doc. 07–3100 Filed 06–22–07; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold its thirteenth meeting. The meeting will be open to the public.

DATES: The meeting will be held on Monday July 30, 2007, from 8:30 a.m. until 5 p.m. and Tuesday, July 31, 2007, from 8:30 a.m. until 4:45 p.m.

ADDRESSES: The Sheraton National Hotel, 900 South Orme Street, Arlington, VA 22204. Phone: 703–521–1900.

FOR FURTHER INFORMATION CONTACT: Bernard Schwetz, D.V.M., PhD, Director, Office for Human Research Protections (OHRP), or Catherine Slatinshek, Executive Director, Secretary's Advisory Committee on Human Research Protections; Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; 240–453–8139; fax: 240–453–6909; e-mail address: *sachrp@osophs.dhhs.gov*.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

On July 30, 2007, SACHRP will receive and discuss updated information and a report from the Subpart A Subcommittee on issues involving the application of subpart A of 45 CFR part 46 in the current research environment. This subcommittee was established by SACHRP at its October 4–5, 2006, meeting. The Committee also will receive a report and action list from the Subcommittee on Inclusion of Individuals with Impaired Decision-Making in Research. This subcommittee was formed as a result of discussions during the July 31–August 1, 2006, SACHRP meeting. In addition, the Committee will receive a briefing on the Final Report of the National Conference on Institutional Review Boards, held in Washington, DC in November 2006.

On July 31, 2007, the Committee will receive presentations and hear discussions from representatives on a panel that will examine issues involving informed consent, including length and complexity of informed consent documents, views from subjects on these issues, and insights from the human subjects research community. The Committee will also hear presentations from panelists on diversity of ethnic and racial representation in clinical trials.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business Friday, July 20, 2007. Information about SACHRP and the draft meeting agenda will be posted on the SACHRP Web site at: *http://www.hhs.gov/ohrp/sachrp/index.html.*

Dated: June 20, 2007.

Bernard A. Schwetz,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. E7–12229 Filed 6–22–07; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Joy Bryant, University of Oklahoma Health Sciences Center: Based on the report of an investigation conducted by the University of Oklahoma Health Sciences Center (OUHSC) and additional analysis conducted by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Joy Bryant, Tribal Efforts Against Lead (TEAL) phlebotomist, OUHSC, engaged in scientific misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES008755.

Specifically, Ms. Bryant falsified research in the TEAL study by substituting or conspiring with another phlebotomist to substitute her blood or blood of another phlebotomist for blood samples of 10–15 child participants in the TEAL study.

Ms. Bryant has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007:

(1) To exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR part 376, *et seq.*; and

(2) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John E. Dahlberg,

Acting Director, Office of Research Integrity.

[FR Doc. E7–12173 Filed 6–22–07; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Diana Layman, University of Oklahoma Health Sciences Center: Based on the report of an investigation conducted by the University of Oklahoma Health Sciences Center (OUHSC) and additional analysis conducted by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Diana Layman, Tribal Efforts Against Lead (TEAL) phlebotomist, OUHSC, engaged in scientific misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES008755.

Specifically, Ms. Layman falsified research in the TEAL study by substituting or conspiring with another phlebotomist to substitute her blood or blood of another phlebotomist for blood samples of 10–15 child participants in the TEAL study. Ms. Layman has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007:

(1) To exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR part 376, *et seq.*; and

(2) To exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John E. Dahlberg,

Acting Director, Office of Research Integrity.

[FR Doc. E7–12170 Filed 6–22–07; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Availability of Funding Opportunity Announcement

Purpose of Notice: Availability of funding opportunity announcement.

Funding Opportunity Title/Program Name: Nursing Home Diversion Modernization Grant.

Announcement Type: Initial Announcement.

Funding Opportunity Number: HHS–2006–AoA–CD–0713.

Statutory Authority: The Older Americans Act, Public Law 109–365.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.048, Title IV and Title II, Discretionary Projects.

DATES: The deadline date for the submission of applications is August 24, 2007.

I. Funding Opportunity Description

This Program Announcement provides an opportunity for State Units on Aging (SUA) in partnership with Area Agencies on Aging (AAA) to collaborate with aging service provider organizations, and other long-term care stakeholders to modernize and transform their existing Older Americans Act Title IIIB, IIIE, and Alzheimer's Disease Demonstration Grant (ADDGS) funds, and other non-Medicaid state revenue sources, into flexible, consumer directed service dollars that support nursing home diversion programs consistent with the standards described on the *Nursing Home Diversion Modernization Grant Announcement Resource Page* (*http://www.aoa.gov/doingbus/fundopp/announcements/2007/NHDP_Resource_Page.doc*).

While statewide implementation of nursing home diversion programs should be a long-term goal of programs funded under this announcement, a SUA, working with at least one AAA, may propose a project within the AAA's geographic area of the state. States with a single Planning and Service Area (PSA) may propose activities targeted to a single county or region of the state.

A detailed description of the funding opportunity may be found at *http://www.grants.gov* or at *http://www.aoa.gov* on the *AoA Grant Programs Funding Opportunity webpage* (*http://aoa.gov/doingbus/fundopp/fundopp.asp*).

II. Award Information

1. Funding Instrument Type

These grants will be issued as Cooperative Agreements because AoA anticipates having substantial involvement with the recipients during performance of funded activities. This involvement may include: assisting the project leadership in understanding the strategic goals and objectives, policy perspectives, and priorities of the Assistant Secretary for Aging and the AoA by sharing such information on an ongoing basis via e-mail, conference calls, briefings, and other consultations; providing technical assistance and support on grant management and implementation issues, including execution of the cooperative agreement; defining project performance criteria and expectations; and, monitoring, evaluating and supporting the projects' efforts in achieving performance goals.

2. Anticipated Total Priority Area Funding per Budget Period

AoA intends to make available, under this program announcement, grant awards for up to $500,000 each for to up to 12 States at a total federal share of approximately $5,000,000 for an 18 month project period.

III. Eligibility Criteria and Other Requirements

1. Eligible Applicants

Eligibility for grant awards is limited to State Units on Aging.

2. Cost Sharing or Matching

Grantees are required to provide at least 25 percent of the total program costs from non-federal cash or in-kind resources in order to be considered for the award.

3. DUNS Number

All grant applicants must obtain a D–U–N–S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number is free and easy to obtain from *http://www.dnb.com/US/duns_update/*.

4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Application and Submission Information

1. Address To Request Application

Application kits are available by writing to the U.S. Department of Health

and Human Services, Administration on Aging, Richard Nicholls, Center for Planning and Policy Development, Washington, DC 20201, at (202) 357–0152, *richard.nicholls@aoa.hhs.gov,* or online at *http://www.grants.gov* or *http://www.aoa.gov/doingbus/fundopp/fundopp.asp.*

2. Address for Application Submission

Applications must be submitted electronically to *http://www.grants.gov.* In order to be able to submit the application, you must register in the Central Contractor Registry (CCR) database. Information about CCR is available at *http://www.grants.gov/CCRRegister.* Instructions for electronic submission of grant applications are available at *http://www.grants.gov.*

3. Submission Dates and Times

To receive consideration, applications must be submitted electronically by midnight Eastern time by the deadline listed in the **DATES** section at the beginning of this Notice.

4. Information Teleconference

An open information teleconference for applicants of this solicitation will be held July 11, 2007 at 3 p.m., EST. The toll-free teleconference phone number will be (888) 381–5770, passcode: 9559261, leader name: John Wren. For information about the call, contact: U.S. Department of Health and Human Services, Administration on Aging, Linda Velgouse, Center for Planning and Policy Development, Washington, DC 20201, *linda.velgouse@aoa.hhs.gov,* or (202) 357–3427.

V. Responsiveness Criteria

Each application submitted will be screened to determine whether it was received by the closing date and time. Applications received by the closing date and time will be screened for completeness and conformity with the requirements outlined in Sections III and IV of this Notice and the Program Announcement. Only complete applications that meet these requirements will be reviewed and evaluated competitively.

VI. Application Review Information

Eligible applications in response to this announcement will be reviewed according to the following evaluation criteria:

A. Demonstration of an accurate understanding of AoA's vision for Nursing Home Diversion Programs, including the key design elements described in Attachment A, and how nursing home diversion programs targeted at individuals who are not eligible for Medicaid fit into the larger long-term care policy environment, and state long-term care reform/rebalancing efforts;

B. The degree of progress anticipated during the 18 month project period, compared to the ''status quo'' in the State and in the geographic area where the project will be implemented, in transforming existing OAA and other non-Medicaid funding to reflect the standards described in Attachment A;

C. The likelihood that the project, based on the information provided in the application and consistent with the standards in Attachment A, will be able—by the end of the 18 month grant period—to be:

1. Serving consumers with flexible service options that are not limited to any particular service or package of services with funds from Title III–B, III–E, ADDGS, and/or other non-Medicaid programs;

2. Using targeting criteria that allow the project to effectively identify and serve individuals who are at risk of nursing home placement and spend down to Medicaid; and,

3. Using a Single Entry Point system to perform the functions of client screening, assessment, care planning, and the targeting of services to individuals who are at-risk of nursing home placement and spend-down to Medicaid;

D. The likelihood that the project will actually succeed in achieving all its goals and objectives, based on the proposed approach, the project work plan, the involvement of key stakeholders, and other information contained in the application;

E. The likelihood, based on the information contained in the application, that the changes resulting from the project will be sustained beyond the grant period, as well as the degree to which the changes are likely to be incorporated into the state's overall system of long-term care.

VII. Agency Contacts

Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration on Aging, Linda Velgouse, Center for Planning and Policy Development, Washington, DC 20201, at (202) 357–3427, or *linda.velgouse@aoa.hhs.gov.*

Dated: June 20, 2007.

John Wren,

Deputy Assistant Secretary for Management.

[FR Doc. E7–12276 Filed 6–22–07; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–07–06BM]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Randomized Controlled Trial of Routine Screening for Intimate Partner Violence—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Intimate partner violence (IPV) is a prevalent problem with serious health consequences that include death, physical injury, increased rates of physical illness, post-traumatic stress, increased psychological distress, depression, substance abuse, and suicide. Some studies suggest that abuse perpetrated by intimate partners tends to be repetitive and escalates in severity over time. This research has been the basis for promoting early diagnosis and intervention.

Health care providers appear to be well situated to identify IPV. Women come into contact with health care services routinely for a number of reasons such as prenatal care, family planning, cancer screening, and well baby care. Women experiencing IPV make more visits to emergency departments, primary care facilities, and mental health agencies than non-abused women. Considering the magnitude and severity of IPV, and the potential role health care providers could play in reducing its serious consequences, numerous professional and health care organizations have recommended routine screening of women for IPV in primary care settings. However, various systematic reviews of the literature have not found evidence for the effectiveness

of screening to improve outcomes for women exposed to IPV.

Based on the recommendations of a recent expert panel, in order to provide this evidence we are proposing to conduct a randomized controlled trial. The trial will recruit 3680 women in a public obstetrics, gynecology, and family planning clinic. Women attending this clinic tend to be African American and of lower socioeconomic status. For this study (the Main Study), women will be randomly allocated to one of three arms: (1) Screened for IPV, and if disclosing IPV, provided information on available IPV services; (2) not screened and all receiving information on available IPV services; or (3) a control group that will not be screened nor receive information on available IPV services. All three arms will be assessed with a self-report measure for mental health, disability, and quality of life at baseline utilizing an audio-computer-assisted structured interview (A–CASI) and at a 12-month follow-up utilizing a computerized-assisted telephone interview (CATI). A pretest with 196 women in this same clinic will be conducted to test the enrollment, randomization, interview, and follow-up procedures; provide estimates for outcome measures and a potential mediator of outcomes (contact of IPV services); and establish the concordance between measures used at baseline (in the clinic) and at a one-week follow-up over the phone. The study arms of the Pretest, which vary slightly from those of the Main Study, are designed to accomplish these intermediate objectives. The results will be used to refine the measures, procedures, and sample size requirements for the Main Study. The results from the Main Study, the Randomized Controlled Trial, will guide CDC as well as other governmental agencies, professional and health care organizations, and women's advocate groups in formulating its recommendations and policies regarding routine screening.

There are no costs to respondents other than their time to participate in the survey. The total estimated annualized burden hours are 717.7.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondents	Average burden per response (in hours)
Potential Eligibility for Pretest	210	1	1/60
Pretest Baseline Participants	196	1	15/60
Pretest Follow-up Participants	176	1	12/60
Potential Eligibility for Main Study	4600	1	1/60
Main Study Baseline Participants	3680	1	17/60
Main Study Follow-up Participants	2580	1	22/60

Dated: June 19, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–12241 Filed 6–22–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panels (SEP): Risk Factors for Birth Defects, Request for Application (RFA) DD 07–001

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Time and Date: 9 a.m.–5 p.m., August 1, 2007 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to ''Risk Factors for Birth Defects,'' RFA DD 07–001.

Contact Person for More Information: Juliana Cyril, Ph.D., Scientific Review Administrator, Office of Public Health Research, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone 404–639–4639.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 18, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–12222 Filed 6–22–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Graduate Student Training Program Application

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Graduate Partnerships Program/OITE/OIR/OD, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Graduate Student Training Program Application. *Type of Information Collection Request:* Revision. *Form Number:* 0925–0501. *Expiration Date:* November 30, 2007. *Need and Use of Information Collection:* The information gathered in the Graduate Student Training Program application will enable the evaluation and identification of graduate students wishing to perform part or all of their PhD dissertation research within the

NIH Intramural Research Program (NIH–IRP). The application for admission into the Graduate Partnerships Program (GPP) models many university graduate school applications, key areas including: Contact information, citizenship status, identification of partnerships to which the student wishes to apply, educational history, standardized examination scores, letters of recommendation, research interests, personal statement / proposed research, and NIH investigator for dissertation research. In addition, race, ethnicity, gender, and disability questions are included though optional for completion; used only for statistical purposes in evaluating GPP recruiting efforts and compliance with federal regulations. The Graduate Student Training Program application will be used by the NIH Admission Committees to identify candidates for admission in institutional and individual partnerships.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Students pursuing an advanced degree, Ph.D., who would like to perform part or all of their dissertation research in the NIH Intramural Research Program laboratories.

The annual reporting burden is displayed in the following table:

ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Graduate Student Applicants On-Line	100	1	0.50	50
Post-baccalaureate Applicants On-Line	500	1	0.50	250
Collection & Submission of Hardcopy Documents	600	1	0.50	300
Recommendations (600 × 3)	1800	1	0.25	450
Feedback Questions	200	1	0.25	50
Totals	3200			1100

Estimates of capital costs, operating costs, and/or maintenance costs are displayed in the following table:

ESTIMATE OF ANNUAL COST TO THE FEDERAL GOVERNMENT

Annualized capital, start-up cost	Amount	Operational/maintenance & purchase components	Amount
Information Collection	$0.00	Trouble-shooting and monitoring fees	$2000.00
Application Design, Development, Testing	12,000.00	Maintenance	1000.00
Total	12,000.00	Total	3,000.00

Estimate of Other Total Annual Cost Burden: $15,000.00.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Patricia Wagner, Director of Admissions & Registrar, Graduate Partnerships Program, National Institutes of Health, 2 Center Drive, Building 2 / Room 2E12, Bethesda, Maryland 20892–0234, or call 301–594–9603 or E-mail your request, including your address to: *wagnerpa@od.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: June 18, 2007.

Michael M. Gottesman,

Deputy Director for Intramural Research, National Institutes of Health.

[FR Doc. E7–12175 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the

Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Zscan4: A Gene Critical for Early Embryonic Development

Description of Technology: Activation of transcription from the embryonic genome, known as zygotic genome activation (ZGA), marks the key switch from maternal to embryonic control of development and establishes gene expression patterns required for continued development of the embryo. Genes expressed during ZGA may be important for assisted reproductive technologies, and in stem cell research and development.

The inventors have identified Zscan4, a gene expressed solely in late 2-cell stage embryos and in embryonic stem cells. Inhibition of Zscan4 expression using siRNA techniques delays progression from the 2-cell stage to the 4-cell stage, and produces blastocysts that fail to implant in the mouse embryo. Thus, Zscan4 plays an essential role in early embryonic development, with potential applications for the development of stem cell therapeutics. The invention discloses methods of promoting blastocyst outgrowth of embryonic stem cells. Also disclosed are Zscan4 expression vectors and methods of identifying a subpopulation of stem cells expressing Zscan4.

Applications: Development of stem cell therapeutics; Assisted reproduction technologies and studies of early embryonic development.

Market: State and federal funding for stem cell research is predicted to reach $10 billion by 2018.

Development Status: Early stage.

Inventors: Minoru S. Ko *et al.* (NIA).

Publications: Geppino Falco *et al.* Zscan4: A novel gene expressed exclusively in late 2-cell embryos and embryonic stem cells. Dev Biol., in press.

Patent Status: U.S. Provisional Application No. 60/920,215 filed 26 Mar 2007 (HHS Reference No. E–088–2007/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Tara L. Kirby, Ph.D.; 301/435–4426; *tarak@mail.nih.gov.*

Retrovirus Packaging Cell Lines Based on Gibbon Ape Leukemia Virus

Description of Technology: Gene therapy and gene transfer have recently been recognized as effective therapeutic tools to combat diseases. Accordingly, market demands for vectors and carriers to facilitate such interventions have surged in recent years. Retroviral vectors provide an efficient and safe means of gene transfer to eukaryotic cells. The present invention relates to genetic engineering involving retrovirus packaging cells that produce retroviral vectors. Specifically, the invention involves the expression plasmids encoding the envelope glycoproteins of a family of primate type C retrovirus, namely, the Gibbon Ape leukemia virus (GALV). Recombinant vectors derived from murine leukemia virus (MLV) have been widely used to introduce genes in human gene therapy clinical trials. A key determinant for their use in clinical gene therapy is the availability of packaging cell lines capable of producing large amounts of virus with identical titers. The present invention describes the packaging cell lines that produce MLV-based gene transfer vectors with the envelope from gibbon ape leukemia virus. Retroviral vectors produced are of high titer and have an expanded host range providing a means for gene transfer to a wide range of animal species. The gene transfer vectors produced are non-infectious and there was no evidence of production of helper virus, making these vectors safe. These cell lines are critical for producing large amounts of standardized vector necessary for efficient in vivo and ex vivo gene transfer. Therefore, this invention has a significant commercial application as a tool in the development of diagnostic and therapeutic interventions related to gene transfer and gene therapy.

Inventors: Maribeth V. Eiden (NIMH) *et al.*

Patent Status: U.S. Patent No. 5,470,726 issued 28 Nov 1995 (HHS Reference No. E–201–1991/0–US–02).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Tara L. Kirby, Ph.D.; 301/435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Mental Health, Laboratory of Cellular and Molecular Regulation, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the Gibbon Ape leukemia virus (GALV) packaging cell line. Please contact Suzanne Winfield at *winfiels@mail.nih.gov* for more information.

Dated: June 14, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–12174 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center on Minority Health and Health Disparities Special Emphasis Panel; NCMHD Conference Grant Application.

Date: July 19, 2007.

Time: 8 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Robert Nettey, MD, Scientific Review Administrator, National Institute on Minority Health, and Health Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, 301–496–3996.

Dated: June 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3080 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be open to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; National Cooperative Drug Discovery Group.

Date: July 17, 2007.

Time: 1:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Vinod Charles, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892–9606, 301–443–1606.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: June 18, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3074 Filed 6–22–07; 8:45 am]

BILLING CODE4140–07–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice if hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Alcohol and Diabetes Ancillary Studies.

Date: July 27, 2007.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 18, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3075 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–07–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Identification of Single Nucleotide Polymorphisms (SNPs) in Disease Susceptibility Genes.

Date: July 31, 2007.

Time: 10:30 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–0752, *mcgee1@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: June 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3077 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 19(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Mentored Clinical Investigator Award (K08) & Small Grant (R03) Applications Review.

Date: July 13, 2007.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *Is38oz@nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Adolescent Bariatrics Ancillary Studies.

Date: July 20, 2007.

Time: 3 p.m. to 4 p.m.

Agenda To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Risk for Human SLE Nephritis.

Date: July 23, 2007.

Time: 3 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Robert Wellner, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, *rw175w@nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Hematopoietic Cell Transplantation.

Date: July 25, 2007.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy Plaza Two, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Robert Wellner, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, *rw175w@nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Cardiovascular Studies in Type 2 Diabetes Ancillary Studies.

Date: July 26, 2007.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy Plaza Two, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Robert Wellner, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 757, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, *rw175w@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3081 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Mechanisms of Preeclampsia: Impact of Obesity.

Date: July 17, 2007.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Dennis E. Leszczynski, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Blvd., Rm. 5B01, Bethesda, MD 20892, (301) 435–6884, *leszczyd@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3082 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; MBRS Support of Competitive Research.

Date: July 9, 2007.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3AN–18, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person; Rebecca H. Johnson, PhD, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18, Bethesda, MD 20892, 301–594–2771, *johnsonrh@nigms.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry

Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3083 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Translational Research in Integrative Behavioral Science.

Date: July 16, 2007.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Vinod Charles, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892–9606, 301–443–1606.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; HTS Assay Development 2.

Date: July 18, 2007.

Time: 8:30 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Yong Yao, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9606, Bethesda, MD 20892–9606, 301–443–6102, *yyao@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; HTS Assay Development 1.

Date: July 18–19, 2007.

Time: 9:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Yong Yao, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9606, Bethesda, MD 20892–9606, 301–443–6102, *yyao@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; AIDS UO1: Review Group 1.

Date: August 13, 2007.

Time: 9 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications. National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Henry J. Haigler, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6150, MSC 9608, Bethesda, MD 20892–9608, 301–443–7216, *hhaigler@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: June 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3084 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 28, 2007, 1 p.m. to June 28, 2007, 3 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on June 11, 2007, 72 FR 32129–32131.

The meeting will be held July 23, 2007, from 1 p.m. to 4 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: June 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3076 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Immunotherapy.

Date: June 27, 2007.

Time: 3 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sharon K. Gubanich, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, (301) 435–1767, *gubanics@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Skeletal Muscle and Exercise Physiology.

Date: July 3, 2007.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: John P. Holden, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, (301) 496–8551, *holdenjo@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Brain Disorders and Clinical Neuroscience.

Date: July 9, 2007.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington Embassy Row, 2015 Massachusetts Ave., NW., Washington, DC 20036.

Contact Person: Suzan Nadi, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217B, MSC 7846, Bethesda, MD 20892, (301) 435–1259, *nadis@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Drug Development and Therapeutics SBIR/STTR ONC–V (13).

Date: July 10–12, 2007.

Time: 8:30 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Steven B. Scholnick, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7804, Bethesda, MD 20892, 301–435–1719, *scholnis@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Brain Disorders and Clinical Neuroscience.

Date: July 10, 2007.

Time: 1 p.m. to 4 p.m.

Agenda: to review and evaluate grant applications.

Place National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contract Person: Alexander Yakovlev, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892 301–435–1254, *yakovleva@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Atherosclerosis and Lipoprotein Receptors.

Date: July 16, 2007.

Time: 1:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Anshumali Chaudhari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, *chaudhaa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Rehabilitation Sciences.

Date: July 18, 2007.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jo Pelham, BA, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435–1786, *pelhamj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Biophysical and Physiological Neuroscience.

Date: July 19, 2007.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Jurys Washington Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Contact Person: Michael A. Lang, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7850, Bethesda, MD 20892, (301) 435–1265, *langm@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group, AIDS Discovery and Development of Therapeutics Study Section.

Date: July 24, 2007.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Union Square, 480 Sutter Street, San Francisco, CA 94108.

Contact Person: Shiv A. Prasad, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Instrumentation for Proteomic Approaches.

Date: July 24–25, 2007.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Nuria E. Assa-Munt, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts in Developmental Disability.

Date: July 24, 2007.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Luci Roberts, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188, MSC 7848, Bethesda, MD 20892, (301) 435–0692, *roberlu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurotechnology/Engineering SEP.

Date: July 25, 2007.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate Hotel, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Robert C. Elliott, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, 301–435–3009, elliotro@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS-associated Opportunistic Infections and Cancer Study Section.

Date: July 25, 2007.

Time: 8 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Union Square, 480 Sutter Street, San Francisco, CA 94108.

Contact Person: Eduardo A. Montalvo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5212, MSC 7852, Bethesda, MD 20892, 301–435–1168, *montalve@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Exploratory Applications in Child Psychopathology.

Date: July 25–26, 2007.

Time: 8 a.m. to 9 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jane A. Eoussard-Roosevelt, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, 301–435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug Discovery.

Date: July 26–27, 2007.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate Hotel, 2650 Virginia Avenue, NW, Washington, DC 20037.

Contact Person: Mary Custer, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4180, MSC 7850, Bethesda, MD 20892, 301–435–1164, *custerm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cardiac Repair and Vascular Cell Signaling.

Date: July 26–27, 2007.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajiv Kumar, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7802, Bethesda, MD 20892, 301–435–1212, *kumarra@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Erythrocyte Biology.

Date: July 27, 2007.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert T. Su, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4134, MSC 7802, Bethesda, MD 20892, 301–435–1195, *sur@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3078 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 11, 2007, 1 p.m. to July 11, 2007, 5 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on June 11, 2007, 72 FR 32129–32131.

The meeting will be held July 30, 2007, from 12 p.m. to 5 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: June 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–3079 Filed 6–22–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[COTP Houston-Galveston–07–015]

Houston/Galveston Navigation Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meetings.

SUMMARY: On May 11, 2007, the Coast Guard announced that the Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC) and its working groups would meet to discuss waterway improvements, aids to navigation, area projects impacting safety on the Houston Ship Channel, and various other navigation safety matters in the Galveston Bay area. This notice supplements that original meeting notice.

DATES: The HOGANSAC meeting was held on Tuesday, May 22, 2007 at 9 a.m. The meeting of the Committee's working groups was held on Tuesday, May 8, 2007 at 9 a.m. Members of the public may present written or oral statements at either meeting. Requests to make oral presentations or distribute written materials should reach the Coast Guard five (5) working days before the meeting at which the presentation will be made. Requests to have written materials distributed to each member of the committee in advance of the meeting should reach the Coast Guard at least ten (10) working days before the meeting at which the presentation will be made.

ADDRESSES: The full Committee meeting was held at the Houston Pilots Association, 8150 South Loop East, Houston, Texas 7701–1747, (713) 645–9620. The working groups meetings were held at the Foret Enterprises, Inc., 15201 East Freeway, Suite 109, Channelview, Texas 77530, (281) 452–9940. This notice is available on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Commander Jerry Torok, Executive Secretary of HOGANSAC, telephone (713) 671–5164, or Lieutenant Jon Stewart, Assistant to the Executive Secretary of HOGANSAC, telephone (713) 678–9001, e-mail *jon.d.stewart@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2.

The meeting agendas were published as part of the original notice on May 1, 2007, which may be found in the **Federal Register** at 72 FR 26822. The Federal Advisory Committee Act requires **Federal Register** publication 15 days prior to a meeting held in accordance with the Act. The original HOGANSAC meeting announcement was published in the **Federal Register** 11 days prior to the meeting due to the unavailability of the committee sponsor to sign the notice. Although the meeting notice published in the **Federal Register** late, the Coast Guard Sector Houston/Galveston made notice to the public via the Coast Guard's Homeport notification system, publication of the meeting in trade journals, and local maritime publications. All interested parties were made aware of the meetings with sufficient time for planning purposes.

Dated: May 18, 2007.

William J. Diehl,

Captain, U.S. Coast Guard, Captain of the Port Houston-Galveston.

[FR Doc. E7–12147 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed revised information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning information required by FEMA to amend or revise National Flood Insurance Program (NFIP) Maps to remove certain property from the 1-percent annual chance floodplain.

SUPPLEMENTARY INFORMATION: With the passage of the Flood Disaster Protection Act of 1973, an owner of a structure, with a federally backed mortgage, located in the 1-percent annual chance floodplain, was required to purchase federal flood insurance. This was in response to the escalating damage caused by flooding and the unavailability of flood insurance from commercial insurance companies. As part of this effort, FEMA mapped the 1-percent annual chance floodplain in communities. However, due to scale limitations, individual structures that may be above the base flood cannot always be shown as being out of the 1-percent annual chance floodplain. FEMA will issue a Letter of Map Amendment (LOMA) or a Letter of Map Revision—Based on Fill (LOMR–F) to waive the Federal requirement for flood insurance when data is submitted to

show that the property or structure is ''reasonably safe from flooding'' and at or above the elevation of the base flood. Requestors can check on the status of their Letter of Map Amendment (LOMA), Letter of Map Revision Based on Fill (LOMR–F), Conditional Letter of Map Amendment (CLOMA), and Conditional Letter of Map Revision Based on Fill (CLOMR–F) request by visiting FEMA's Mapping Information Platform Web site at *https://hazards.fema.gov.*

Collection of Information

Title: Revisions to National Flood Insurance Program Maps: Application Forms and Instructions for (C)LOMAs and (C)LOMR–Fs.

Type of Information Collection: Revision of a currently approved collection.

OMB Number: 1660–0015.

Form Numbers: FEMA Forms 81–87, 81–87A, 81–87B.

Abstract: The certification forms (referred to as MT–1 series forms) are designed to assist requesters in gathering information that the FEMA needs to determine whether a certain property is likely to be flooded during a flood event that has a one-percent annual chance of being equaled or exceeded in any given year (base flood). FEMA Form 81–87, Property Information, describes the location of the property, what is being requested, and what data are required to support the request. FEMA Form 81–87A, Elevation Information, indicates what the Base (one-percent annual chance) Flood Elevation (BFE) for the property is, how the BFE was determined, the lowest ground elevation on the property, and/or the elevation of the lowest adjacent grade to any structures on the property. This information is required in order for FEMA to determine if the property that the requester would like removed from the Special Flood Hazard Area (SFHA) is at or above the BFE. FEMA Form 81–87B, Community Acknowledgment, requires that a community official certify that the request complies with minimum floodplain management criteria specified in 44 CFR 60.3, as per NFIP regulations 44 CFR 65.5(a)(4).

Affected Public: Individuals or households, business or other for-profit organizations, and state and local or tribal government.

Estimated Total Annual Burden Hours: 58,150.

ANNUAL BURDEN HOURS

Project/activity (survey, form(s), focus group, worksheet, etc.)	Number of respondents	Frequency of responses	Burden hours per respondent	Annual responses	Total annual burden hours
	(A)	(B)	(C)	(D) = (A×B)	(E) = (C×D)
Form 81–87, Property Information Form (Homeowners/ Representatives of Homeowner).	18,272	Annual (1) ...	1.63	18,272	29,783
Form 81–87A, Elevation Form (Surveyors/Engineers)	18,272	Annual (1) ...	1.25	18,272	22,840
Form 81–87B, Community Acknowledgment Form (Community Officials).	3,389	Annual (1) ...	1.38	3,389	4,677
On-line LOMA/LOMR-F Tutorial (Homeowners)	1,700	Annual (1) ...	0.5	1,700	850
Total	41,633	.....	4.76	19,972*	58,150

*The total number of annual responses represents the total number of collection packages received. Estimated number of collection packages received in a given year is 19,972.

Estimated Cost: Cost to respondents is estimated to be $1,258,199 annually.

Comments: Written comments are solicited to (a) Evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Comments must be submitted on or before August 24, 2007.

ADDRESSES: Interested persons should submit written comments to Chief, Records Management and Privacy, Information Resources Management Branch, Information Technology Services Division, Federal Emergency Management Agency, 500 C Street, SW., Room 609, Washington, DC 20472.

FOR FURTHER INFORMATION CONTACT: Contact Ms. Cecelia Lynch, FEMA, Federal Insurance and Mitigation Administration at (202) 646–7045 for additional information. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *FEMA-Information-Collections@dhs.gov.*

Dated: June 13, 2007.

John A. Sharetts-Sullivan,

Chief, Records Management and Privacy, Office of Management Directorate, Information Technology Services Division, Information Resources Management Branch, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E7–12200 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1605–DR]

Alabama; Amendment No. 10 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Alabama (FEMA–1605–DR), dated August 29, 2005, and related determinations.

DATES: *Effective Date*: May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care,

Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on August 29, 2005 for the State of Alabama due to damage resulting from Hurricane Katrina. The Alabama major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12195 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1593–DR]

Alabama; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Alabama (FEMA–1593–DR), dated July 10, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007,'' Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on July 10, 2005 for the State of Alabama due to damage resulting from Hurricane Dennis. The Alabama major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12201 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1700–DR]

Connecticut; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Connecticut (FEMA–1700–DR), dated May 11, 2007, and related determinations.

DATES: *Effective Date:* June 13, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Connecticut is hereby amended to include the Individual Assistance program for the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 11, 2007.

Hartford, Middlesex, New Haven, New London, and Windham Counties for Individual Assistance.

Fairfield and Litchfield Counties for Individual Assistance (already designated for Public Assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12202 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1602–DR]

Florida; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida (FEMA–1602–DR), dated August 28, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007,'' Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on August 28, 2005 for the State of Florida due to damage resulting from Hurricane Katrina. The Florida major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12198 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1609–DR]

Florida; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida (FEMA–1609–DR), dated October 24, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on October 24, 2005 for the State of Florida due to damage resulting from Hurricane Wilma. The Florida major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12203 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1595–DR]

Florida; Amendment No. 9 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida (FEMA–1595–DR), dated July 10, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007,'' Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172,5173 and 5174, for a major disaster declared on July 10, 2005 for the State of Florida due to damage resulting from Hurricane Dennis. The Florida major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public

assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12204 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1699–DR]

Kansas; Amendment No. 8 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Kansas (FEMA–1699–DR), dated May 6, 2007, and related determinations.

DATES: *Effective Date:* June 15, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Kansas is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of May 6, 2007.

Osage County for Individual Assistance (already designated for Public Assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050, Individuals and Households Program—Other Needs; 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12277 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1607–DR]

Louisiana; Amendment No. 17 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Louisiana (FEMA–1607–DR), dated September 24, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on September 24, 2005 for the State of Louisiana due to damage resulting from Hurricane Rita. The Louisiana major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12209 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1603–DR]

Louisiana; Amendment No. 12 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Louisiana (FEMA–1603–DR), dated August 29, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided

under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on September 24, 2005 for the State of Louisiana due to damage resulting from Hurricane Katrina. The Louisiana major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12211 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1604–DR]

Mississippi; Amendment No. 15 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Mississippi (FEMA–1604–DR), dated August 29, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on September 24, 2005 for the State of Mississippi due to damage resulting from Hurricane Katrina. The Mississippi major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12199 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1594–DR]

Mississippi; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Mississippi (FEMA–1594–DR), dated July 10, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on July 10, 2005 for the State of Mississippi due to damage resulting from Hurricane Dennis. The Mississippi major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and

Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program-Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12206 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[FEMA–1606–DR]

Texas; Amendment No. 10 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Texas (FEMA–1606–DR), dated September 24, 2005, and related determinations.

DATES: *Effective Date:* May 25, 2007.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, Public Law 110–28, FEMA is amending the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5170b, 5172, 5173 and 5174, for a major disaster declared on September 24, 2005 for the State of Texas due to damage resulting from Hurricane Rita. The Texas major disaster declaration is amended as follows:

Federal funds for all categories of Public Assistance, including direct Federal assistance, for which a ''request for public assistance form'' has been submitted as of May 25, 2007 and Other Needs Assistance (Section 408) applied for before May 25, 2007 are authorized at 100 percent of total eligible costs.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act specifically prohibits a similar adjustment for funds provided to States for the Hazard Mitigation Grant Program (Section 404). These funds will continue to be reimbursed at 75 percent of total eligible costs.

This cost share is effective as of the date of the President's major disaster declaration.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–12197 Filed 6–22–07; 8:45 am]

BILLING CODE 9110–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Revision of an Existing Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form I–360, Petition for Amerasian, Widow, or Special Immigrant, OMB Control No. 1615–0020.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on April 9, 2007, at 72 FR 17576. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 25, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352 or via e-mail at *rfs.regs@dhs.gov,* and to the OMB USCIS Desk Officer via facsimile at 202–395–6974 or via e-mail at *kastrich@omb.eop.gov.*

When submitting comments by e-mail, please make sure to add OMB Control Number 1615–0020 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of an existing information collection.

(2) *Title of the Form/Collection:* Petition for Amerasian, Widow, or Special Immigrant.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–360; U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This information collection is used by several prospective classes of aliens who intend to establish their eligibility to immigrate to the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 13,684 responses at 2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 27,368 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please visit the USCIS Web site at: *http://www.uscis.gov/portal/site/uscis/menuitem.eb1d4c2a3e5b9ac89243c6a7543f6d1a/?vgnextoid=29227b58fa16e010VgnVCM1000000ecd190aRCRD&vgnextchannel=29227b58fa16e010VgnVCM1000000ecd190aRCRD.*

If additional information is required, please contact Richard A. Sloan, Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, 111 Massachusetts Avenue, NW., 3rd Floor, Suite 3008, Washington, DC 20529; 202–272–8377.

Dated: June 20, 2007.

Stephen Tarragon,

Deputy Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services.

[FR Doc. E7–12255 Filed 6–22–07; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–32]

Re-Accreditation and Re-Approval of Columbia Inspection as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Columbia Inspection of San Pedro, California, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Columbia Inspection, 797 Channel Street, San Pedro, California 90731, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml.*

DATES: The re-approval of Columbia Inspection as a commercial gauger and laboratory became effective on July 11, 2006. The next triennial inspection date will be scheduled for July 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12254 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–31]

Re-Accreditation and Re-Approval of Chemical and Petrochemical Inspections, LL.P., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Chemical and Petrochemical Inspections, LL.P., of Groves, Texas as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Chemical and Petrochemical Inspections, LL.P., 5300 39th Street, Groves, Texas 77619, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml.*

DATES: The re-approval of Chemical and Petrochemical Inspections, LL.P., as a commercial gauger and laboratory became effective on April 6, 2006. The next triennial inspection date will be scheduled for April 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12256 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–30]

Re-Approval of Certispec Services USA, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Certispec Services USA, Inc., of Texas City, Texas, as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Certispec Services USA, Inc., 1448 Texas Avenue, Texas City, Texas 77590, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity for gauger services should request and receive written assurances from the entity that it is approved by the Bureau of Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger services this entity is approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml.*

DATES: The re-approval of Certispec Services USA, Inc., as a commercial gauger became effective on October 19, 2005. The next triennial inspection date will be scheduled for October 2008.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12258 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–41]

Re-Accreditation and Re-Approval of Saybolt, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Saybolt, Inc., of Pasadena, Texas, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Saybolt, Inc., 3113 Red Bluff Road, Pasadena, Texas 77503, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-approval of Saybolt, Inc., as a commercial gauger and laboratory became effective on September 6, 2006. The next triennial inspection date will be scheduled for September 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12264 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–34]

Re-Accreditation and Re-Approval of Inspectorate America Corporation as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Inspectorate America Corporation of Pasadena, Texas, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Inspectorate America Corporation, 131 Pasadena Boulevard, Pasadena, Texas 77506, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-approval of Inspectorate America Corporation as a commercial gauger and laboratory became effective on September 8, 2006. The next triennial inspection date will be scheduled for September 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12278 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–35]

Re-Approval of Inspectorate America Corporation as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Inspectorate America Corporation of Searsport, Maine, as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, Inspectorate America Corporation, 178 Mortland Road, Searsport, Maine 04974, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity for gauger services should request and receive written assurances from the entity that it is approved by the Bureau of Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger services this entity is approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-approval of Inspectorate Amercia Corporation as a commercial gauger became effective on May 17, 2006. The next triennial inspection date will be scheduled for May 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12266 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–42]

Re-Approval of Sgs North America, Inc., as a Commercial Gauger

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of SGS North America, Inc., of Baytown, Texas, as a commercial gauger.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.13, SGS North America, Inc., Contractor's Row East, ExxonMobil Refinery, Baytown, Texas 77520, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.13. Anyone wishing to employ this entity for gauger services should request and receive written assurances from the entity that it is approved by the Bureau of Customs and Border Protection to conduct the specific gauger service requested. Alternatively, inquiries regarding the specific gauger services this entity is approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-approval of SGS North Amercia, Inc., as a commercial gauger became effective on February 17, 2005. The next triennial inspection date will be scheduled for February 2008.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12267 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–36]

Re-Accreditation and Re-Approval of Inspectorate America Corporation as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Inspectorate America Corporation of South Portland, Maine, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Inspectorate America Corporation, 33 Rigby Road, South Portland, Maine 04106, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-approval of Inspectorate America Corporation as a commercial gauger and laboratory became effective on May 16, 2006. The next triennial inspection date will be scheduled for May 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12273 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection.

[CBP Dec. 07–39]

Re-Accreditation and Re-Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Intertek USA, Inc., of Texas City, Texas as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Intertek USA, Inc., 101 20th Street South, Texas City, Texas 77590, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_/svcs/org_and__operations.xml*.

DATES: The re-approval of Intertek USA, Inc., as a commercial gauger and laboratory became effective on September 27, 2006. The next triennial inspection date will be scheduled for September 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12286 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–38]

Re-Accreditation and Re-Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Intertek USA, Inc., of South Portland, Maine, as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Intertek USA, Inc., 78 Pleasant Avenue, South Portland, Maine 04106, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-approval of Intertek USA, Inc., as a commercial gauger and laboratory became effective on May 15, 2006. The next triennial inspection date will be scheduled for May 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12287 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–37]

Re-Accreditation and Re-Approval of Intertek U.S.A., Inc., as a Commercial Gauger and Laboratory

AGENCY: U. S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-approval of Intertek U.S.A., Inc., of Gonzales, Louisiana as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12 and 151.13, Intertek U.S.A., Inc., 2632 Ruby Avenue, Gonzales, Louisiana 70737, has been re-approved to gauge petroleum and petroleum products, organic chemicals and vegetable oils, and to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 151.13. Anyone wishing to employ this entity to conduct laboratory analysis or gauger services should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific tests or gauger services this entity is accredited or approved to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-approval of Intertek U.S.A., Inc., as a commercial gauger and laboratory became effective on May 3, 2005. The next triennial inspection date will be scheduled for May 2008.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12288 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–40]

Re-Accreditation of Markan Laboratories, Inc., as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-accreditation of Markan Laboratories, Inc., of New York, New York, as an accredited commercial laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12, Markan Laboratories, Inc., 5 Hanover Street, New York, New York 10004, has been re-accredited to test sugar, sugar syrups and confectionary products under Chapter 17 of the Harmonized Tariff Schedule of the United States (HTSUS) for customs purposes, in accordance with the provisions of 19 CFR 151.12. Anyone wishing to employ this entity to conduct laboratory analysis should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test requested. Alternatively, inquiries regarding the specific tests this entity is accredited to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*.

DATES: The re-accreditation of Markan Laboratories, Inc., as an accredited laboratory became effective on February 15, 2005. The next triennial inspection date will be scheduled for February 2008.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, PhD, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12275 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 07–33]

Re-Accreditation of Dixie Services, Inc., as a Commercial Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of re-accreditation of Dixie Services, Inc., of Galena Park, Texas, as an accredited commercial laboratory.

SUMMARY: Notice is hereby given that, pursuant to 19 CFR 151.12, Dixie Services, Inc., 1706 First Street, Galena Park, Texas 77547, has been re-accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12. Anyone wishing to employ this entity to conduct laboratory analysis should request and receive written assurances from the entity that it is accredited or approved by the Bureau of Customs and Border Protection to conduct the specific test requested. Alternatively, inquiries regarding the specific tests this entity is accredited to perform may be directed to the Bureau of Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *http://www.cbp.gov/xp/cgov/import/operations_support/labs_scientific_svcs/org_and_operations.xml*

DATES: The re-accreditation of Dixie Services, Inc., as an accredited laboratory became effective on October 4, 2006. The next triennial inspection date will be scheduled for October 2009.

FOR FURTHER INFORMATION CONTACT: Eugene J. Bondoc, Ph.D, or Randall Breaux, Laboratories and Scientific Services, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Suite 1500N, Washington, DC 20229, 202–344–1060.

Dated: June 18, 2007.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. E7–12283 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[USCBP–2007–0060]

Notice of Availability of a Draft Programmatic Environmental Assessment on the Western Hemisphere Travel Initiative at Land and Sea Ports of Entry

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of Availability.

SUMMARY: This Notice of Availability announces that a draft Programmatic Environmental Assessment (PEA) for the Western Hemisphere Travel Initiative (WHTI) at land and sea ports of entry is available for public review and comment. The draft PEA documents a review of the potential environmental impacts from changes to technology and operations to meet the requirements for standardized, secure travel documents under WHTI.

DATES: The draft PEA will be available for public review and comment for a period of 30 days beginning on the date this document is published in the **Federal Register**. Copies of the draft PEA may be obtained by telephone request (202–344–1589) or by accessing the following Internet addresses: *http://www.cbp.gov/travel* and *http://www.regulations.gov*. Comments regarding the draft PEA may be submitted as set forth in the **ADDRESSES** section of this document.

ADDRESSES: Copies of the draft PEA may be obtained from U.S. Customs and Border Protection (CBP) through the Internet at *http://www.cbp.gov/travel* and *http://www.regulations.gov* or by writing to: CBP, 1300 Pennsylvania Avenue, NW., Room 5.4C, Attn: WHTI Environmental Assessment, Washington, DC 20229.

You may submit comments on the draft PEA, by *one* of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Comments by mail are to be addressed to U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 5.4C, Attn: WHTI Environmental Assessment, Washington, DC 20229.

Instructions: All submissions must include the agency name and draft PEA docket number ''USCBP–2007–0060.'' All comments will be posted without change to *http://www.regulations.gov*, including any personal information sent with each comment.

FOR FURTHER INFORMATION CONTACT: Patrick Howard, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 5.4C, Washington, DC 20229, 202–344–1589, e-mail address: *Patrick.Howard@associates.dhs.gov*, or Pat Sobol, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 5.4C, Washington, DC 20229, 202–344–1381, e-mail address: *Pat.Sobol@dhs.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Western Hemisphere Travel Initiative

The Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), as amended, provides that upon full implementation, U.S. citizens and Bermudian, Canadian and Mexican citizens and nationals would be required to present a passport or such alternative documents as the Secretary of Homeland Security designates as satisfactorily establishing identity and citizenship upon entering the United States. In a notice of proposed rulemaking (NPRM) to be published in the **Federal Register**, the Department of Homeland Security (DHS) and Department of State (DOS) describe the second phase of a joint plan, known as the Western Hemisphere Travel Initiative (WHTI), to implement these new requirements. The NPRM proposes the specific documents that U.S. citizens and nonimmigrant aliens from Canada, Bermuda, and Mexico would be required to present when entering the United States at sea and land ports-of-entry from Western Hemisphere countries.

DHS and CBP have analyzed the potential impacts on the human environment of several alternate ways of implementing WHTI based on technological and operational considerations as part of the decision-making process regarding the implementation of WHTI at sea and land ports of entry. The impact analysis in the draft Programmatic Environmental Assessment (PEA), as explained in the report, focuses primarily on the effects of implementing WHTI at land ports of entry because the land environment is the most sensitive to the proposed document and technological changes associated with implementation of WHTI.[1]

[1] Changes to processing travelers at sea ports of entry would happen entirely within existing

Four technological and operational alternatives are analyzed in the PEA that meet the requirements to define and process secure, standardized travel documents under WHTI. The four alternatives are: (1) Maintaining the status quo by continuing current processes for assessing individuals with multiple documents; (2) implementing standardized features and limiting the number of documents accepted for entry into the United States; (3) defining and enhancing a limited number of standardized acceptable documents with machine readable zone (MRZ) technology; and/or (4) defining and enhancing a limited number of standardized acceptable documents with MRZ and radio-frequency identification (RFID) technologies at the top volume land ports of entry. The potential impacts evaluated include air quality, noise, and environmental justice, among others.

Next Steps

This process is being conducted pursuant to the National Environmental Policy Act of 1969 (NEPA), the Council on Environmental Quality (CEQ) Regulations for Implementing the NEPA (40 CFR parts 1500–1508), and Department of Homeland Security Management Directive 5100.1, *Environmental Planning Program of April 19, 2006.*

Substantive comments concerning environmental impacts received from the public and agencies during the comment period will be evaluated to determine whether further environmental impact review is needed in order to publish the final PEA. Should CBP determine that the implementation of the proposed action or alternatives would not have a significant impact on the environment, it will prepare a Finding of No Significant Impact (FONSI). The FONSI would be published in the **Federal Register** and in newspapers of general circulation in border areas along the border with both Canada and Mexico.

Should CBP determine that significant environmental impacts exist due to the plan, CBP would proceed with preparation of an Environmental Impact Statement (EIS).

Dated: June 19, 2007.

Thomas S. Winkowski,

Acting Assistant Commissioner, Office of Field Operations.

[FR Doc. E7–12274 Filed 6–22–07; 8:45 am]

BILLING CODE 9111–14–P

buildings and other infrastructure, so no environmental impacts are anticipated.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Rice Lake and Mille Lacs National Wildlife Refuges, Aitkin, Pine, and Mille Lacs Counties, MN

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability: Draft comprehensive conservation plan and environmental assessment; request for comments.

SUMMARY: The U.S. Fish and Wildlife Service (Service), announce the availability of a draft comprehensive conservation plan (CCP) and environmental assessment for Rice Lake and Mille Lacs National Wildlife Refuges (NWRs) for public review and comment. In this draft CCP/EA, we describe how we propose to manage these refuges for the next 15 years.

DATES: To ensure consideration, we must receive your written comments by July 30, 2007. Open house style meetings will be held during the comment period to receive comments and provide information on the draft plan. Special mailings, newspaper articles, Internet postings, and other media announcements will inform people of the meetings and opportunities for written comments.

ADDRESSES: Send your comments or requests for more information by any of the following methods. You may also drop off comments in person at Rice Lake NWR.

- *Agency Web site:* View or download a copy of the document and comment at *http://www.fws.gov/midwest/planning/RiceLake/.*
- *E-mail: r3planning@fws.gov.* Include ''Rice Lake Draft CCP/EA'' in the subject line of the message.
- *Fax:* 218–768–3040.
- *Mail:* Refuge Manager, Rice Lake National Wildlife Refuge, 36289 State Hwy 65, McGregor, MN 55760.

FOR FURTHER INFORMATION CONTACT: Walt Ford, 218–768–2402.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we continue the CCP process for Rice Lake and Mille Lacs NWRs, which was started with the notice of intent published in 70 FR 5693 (February 3, 2005). For more about the initial process and the history of these refuges, see that notice. Rice Lake and Mille Lacs NWRs are located in east-central Minnesota. Both refuges are administered by the staff at Rice Lake NWR. Rice Lake NWR is a mosaic of lakes, marshes, forests, and grasslands that provide a variety of habitat for migrant and resident wildlife. The Refuge is especially noted for its fall concentrations of Ring-necked Ducks, which often number over 150,000 birds. The Refuge also includes pre-historic and historic cultural resources of recognized importance. Mille Lacs NWR is the smallest refuge in the National Wildlife Refuge System. The 0.57-acre Refuge consists of two islands in Mille Lacs Lake. One island is managed as a nesting colony for the State-listed threatened Common Tern. The other island is used by other colonial nesting species.

Background

The CCP Process

The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd-668ee), requires us to develop a comprehensive conservation plan for each national wildlife refuge. The purpose in developing a CCP is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, plans identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation, wildlife photography, and environmental education and interpretation.

CCP Alternatives and Our Preferred Alternative

Priority Issues

During the public scoping process, we, other governmental partners, and the public identified several priority issues, which include: Management of the grassland area on auto tour route; management of water levels in Rice Lake; pending Wilderness recommendation; Native American activities on the Refuge; interpretation of cultural resources on the Refuge; unmet demand for interpretation and environmental education; erosion of Hennepin Island (Mille Lacs); operation of the Sandstone Unit. To address these issues, we developed and evaluated the following alternatives during the planning process.

Alternative A, Current Management

Under Alternative A, Current Management, the 170 acres of grassland

on the auto tour route would be maintained; stable water levels in Rice Lake would be maintained throughout the growing season and at sufficient level to allow rice harvest; the 1,400 acre area with the pending Wilderness recommendation would be managed as de facto wilderness; Native American ceremonies would be held under special use permit and wild rice harvest coordinated with local Native American committee; cultural resources would not be interpreted on-site; demand for interpretation and environmental education would be responded to as staff and time permitted; the erosion of Hennepin Island would continue; and the 2005 landcover at the Sandstone Unit would be maintained while allowing for forest succession.

Alternative B, Preferred Alternative

Under Alternative B, Preferred Alternative, 85 acres would be maintained as grassland on the auto tour route to facilitate wildlife observation; water levels would be allowed to fluctuate in Rice Lake to more closely approximate a natural system; the 1,400 acre Wilderness recommendation would be withdrawn to allow for more active management; Native American ceremonies would be held under special use permit and wild rice harvest would be coordinated with local Native American committee; additional interpretation of cultural resources would be developed in cooperation with the Mille Lacs Band of Ojibwe; demand for interpretation and environmental education would be responded to with additional interpretive opportunities and educational programs with the addition of a park ranger position; the erosion of Hennepin Island would be reversed through rebuilding and protection with a constructed reef; and the 2005 landcover at the Sandstone Unit would be maintained while allowing for forest succession.

Public Meeting

We will give the public an opportunity to provide comments at a public meeting. You may obtain the schedule from the addresses listed above (see **ADDRESSES**). You may also submit comments anytime during the comment period.

Public Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should know that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: April 27, 2007.

Charles M. Wooley,

Acting Regional Director, U.S. Fish and Wildlife Service, Fort Snelling, Minnesota.

[FR Doc. E7–12228 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Meeting Announcement: North American Wetlands Conservation Council

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: The North American Wetlands Conservation Council (Council) will meet to select North American Wetlands Conservation Act (NAWCA) grant proposals for recommendation to the Migratory Bird Conservation Commission (Commission). This meeting is open to the public, and interested persons may present oral or written statements.

DATES: July 17, 2007, 1–3 p.m.

ADDRESSES: The meeting will be held at the Best Western Ramkota Inn, 800 South 3rd Street, Bismarck, ND 58504. The meeting is coordinated by the Council Coordinator, located at the U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Mail Stop: MBSP 4501–4075, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Mike Johnson, Council Coordinator, (703) 358–1784 or *dbhc@fws.gov.*

SUPPLEMENTARY INFORMATION: In accordance with NAWCA (Pub. L. 101–233, 103 Stat. 1968, December 13, 1989, as amended), the State-private-Federal Council meets to consider wetland acquisition, restoration, enhancement, and management projects for recommendation to, and final funding approval by, the Commission. Proposal due dates, application instructions, and eligibility requirements are available on the NAWCA Web site at *http://birdhabitat.fws.gov.* Proposals require a minimum of 50 percent non-Federal matching funds. The Council will consider U.S. Standard and Canadian grant proposals at the meeting. The tentative date for the Commission meeting is September 12, 2007.

Dated: June 1, 2007.

Paul Schmidt,

Assistant Director—Migratory Birds.

[FR Doc. E7–12253 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–930–5420–FR–L045; AA–086376—AA–086380]

Notice of Applications for Recordable Disclaimers of Interest for Lands Underlying Waterbodies Within the Yukon-Kuskokwim Portage; Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The State of Alaska (State) has filed applications for Recordable Disclaimers of Interest from the United States in certain lands underlying waterbodies within the Yukon-Kuskokwim Portage, located in the Lower Kuskokwim Region, Alaska. The State asserts that the water bodies were navigable and unreserved at the time of statehood; therefore, title to the submerged lands passed to the State at the time of statehood (1959). The lands included in the applications are within the boundary of the Yukon-Delta National Wildlife Refuge, created by the Alaska National Interest Lands Conservation Act of December 2, 1980.

DATES: Comments on the State of Alaska's applications should be submitted on or before September 24, 2007. The Bureau of Land Management (BLM) Draft Summary Report will be posted on the BLM-Alaska Web-site within this notice period. Once posted, interested parties will have sixty (60) days to comment on the findings: *http://www.blm.gov/ak/ak930/rdi/index.html.*

ADDRESSES: Comments on the State of Alaska's application or the BLM Draft Summary Report should be sent to the Chief, Branch of Lands and Realty, BLM Alaska State Office, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION CONTACT: Jack Frost at (907) 271–5531 or *Jack_Frost@ak.blm.gov* or visit the BLM-Alaska Web site *http://www.blm.gov/ak/ak930/rdi/index.html.*

SUPPLEMENTARY INFORMATION: On March 10, 2006, the State of Alaska filed applications for Recordable Disclaimers of Interest pursuant to Section 315 of the Federal Land Policy and Management Act and the regulations

contained in 43 CFR Subpart 1864 for lands underlying the waterbodies within the Yukon-Kuskokwim Portage (Y–K Portage). The State divided the Y–K Portage into five separate applications, described in a northwesterly direction from the Kuskokwim River: Mud Creek and unnamed lake number one (AA–086376); Crooked Creek and Johnson River (AA–086377); Kulik Lake and unnamed lake number two (AA–086378); unnamed lakes numbers three and four (AA–086379); and the Talbiksok River to the confluence with Portage Slough of the Yukon River (AA–086380). A Recordable Disclaimer of Interest, if issued, will confirm the United States has no valid interest in the subject lands. The notice is intended to notify the public of the pending applications and the State's grounds for supporting it. The State asserts that the water bodies are navigable; therefore, under the Equal Footing Doctrine and Submerged Lands Act of 1953, ownership of these lands automatically passed from the United States to the State at the time of statehood in 1959. The State did not identify any known adverse claimant or occupant of the affected lands. The applied for lands are within the boundary of the Yukon-Delta National Wildlife Refuge, created by the Alaska National Interest Lands Conservation Act of December 2, 1980.

A final decision on the merits of the applications will not be made before September 24, 2007. During the ninety (90) day notice period, interested parties may comment upon the State's applications (AA–086376 to AA–086380), and supporting evidence. Interested parties may also comment on the evidence presented in the BLM Draft Summary Report within sixty (60) days of its availability. The BLM Draft Summary Report will be posted on the BLM-Alaska Web site within the ninety (90) day notice period: *http://www.blm.gov/ak/ak930/rdi/index.html.*

Comments, including names and street addresses of commentors, will be available for public review at the Alaska State Office (see address above), during regular business hours 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 1864.2(a))

Dated: May 4, 2007.

Jack Frost,

Acting Chief, Branch of Lands and Realty.

[FR Doc. E7–12107 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–930–5420–FR–L037; FF–094608—F–094612]

Notice of Applications for Recordable Disclaimers of Interest for Lands Underlying the Kantishna River, Birch Creek, Muddy River, Lake Minchumina, Deep Creek, and Jim Lake; Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The State of Alaska (State) has filed applications for Recordable Disclaimers of Interest from the United States in certain lands underlying waterbodies within the Kantishna River, Birch Creek (a portion thereof), Muddy River, Lake Minchumina, Deep Creek, and Jim Lake in the Tanana River Subregion, Alaska. The State asserts that the water bodies were navigable, and unreserved at the time of statehood; therefore, title to the submerged lands passed to the State at the time of statehood (1959). Some of the lands included in the applications are within the boundary of the Denali National Preserve, created by the Alaska National Interest Lands Conservation Act of December 2, 1980.

DATES: Comments on the State of Alaska's applications should be submitted on or before September 24, 2007. The Bureau of Land Management (BLM) Draft Summary Report will be posted on the BLM-Alaska website within this notice period. Once posted, interested parties will have sixty (60) days to comment on the findings: *http://www.blm.gov/ak/ak930/rdi/index.html.*

ADDRESSES: Comments on the State of Alaska's applications or the BLM Draft Summary Report should be sent to the Chief, Branch of Lands and Realty, BLM Alaska State Office, 222 West 7th Avenue, #13, Anchorage, Alaska 99513–7599.

FOR FURTHER INFORMATION CONTACT: Mike Brown at (907) 271–3602 or visit the BLM–Alaska Web site *http://www.blm.gov/ak/ak930/rdi/index.html.*

SUPPLEMENTARY INFORMATION: On September 29, 2005, the State of Alaska (State) filed five (5) separate applications for Recordable Disclaimers of Interest pursuant to Section 315 of the Federal Land Policy and Management Act and the regulations contained in 43 CFR Subpart 1864 for lands underlying certain waterbodies within the Kantishna River-Lake Minchumina System: Jim Lake (FF–09608); Deep Creek (FF–094609); Muddy River (FF–094610); Lake Minchumina (FF–094611); and the Kantishna River and a portion of Birch Creek (FF–094612). These waterbodies are located within the Tanana River Subregion, Alaska. A Recordable Disclaimer of Interest, if issued, will confirm the United States has no valid interest in the subject lands. The notice is intended to notify the public of the pending applications and the State's grounds for supporting it. The State asserts that the water bodies are navigable; therefore, under the Equal Footing Doctrine and Submerged Lands Act of 1953, ownership of these lands automatically passed from the United States to the State at the time of statehood in 1959. The State did not identify any known adverse claimant or occupant of the affected lands. A portion of the lands included in the applications are within the boundary of the Denali National Preserve, created by the Alaska National Interest Lands Conservation Act of December 2, 1980.

A final decision on the merits of the applications will not be made before September 24, 2007. During the ninety (90) day notice period, interested parties may comment upon the State's applications (FF–094608 to FF–094612), and supporting evidence. Interested parties may also comment on the evidence presented in the BLM Draft Summary Report within sixty (60) days of its availability. The BLM Draft Summary Report will be posted on the BLM-Alaska Web site within the ninety (90) day notice period: *http://www.blm.gov/ak/ak930/rdi/index.html.*

Comments, including names and street addresses of commentors, will be available for public review at the Alaska State Office (see address above), during regular business hours 7:30 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 CFR 1864.2(a))

Dated: May 4, 2007.

Jack Frost,

Acting Chief, Branch of Lands and Realty.

[FR Doc. E7–12153 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–169–1220–AL]

Notice of Public Meeting, Carrizo Plain National Monument Advisory Committee

SUMMARY: In accordance with Federal Land Policy and Management Act of 1976 (FLPMA), the Federal Advisory Committee Act of 1972 (FACA), the National Environmental Policy Act of 1969 (NEPA), and the Code of Federal Regulations (40 CFR 1501.7, 43 CFR 1610.2), the United States Department of the Interior, Bureau of Land Management (BLM), Carrizo Plain National Monument Advisory Committee will meet as indicated below:

DATES: The meeting will be held on Saturday, July 21, 2007, at the Carrisa Plain Elementary School on Highway 58. The school is located approximately 2 miles to the NW of the Soda Lake Road turn-off on Hwy. 58. The meeting will begin at 10 a.m. and finish at 5 p.m. The meeting will focus on the report from the scoping process for the Resource Management Plan/Environmental Impact Statement being developed for the Carrizo Plain National Monument. Public Comment Period 3–4. Lunch will be available for $8.00.

SUPPLEMENTARY INFORMATION: The nine-member Carrizo Plain National Monument Advisory Committee advises the Secretary of the Interior, through the Bureau of Land Management, on a variety of public land issues associated with the public land management in the Carrizo Plain National Monument in central California. At this meeting, Monument staff will present updated information on the progress on the draft Carrizo Plain National Monument Resource Management Plan and the Environmental Impact Statement (RMP/EIS). Reviewing the scoping comments and scoping period will be a focus at this meeting. This meeting is open to the public. Depending on the number of persons wishing to comment, and the time available, the time allotted for individual oral comments may be limited. Individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations should contact BLM as indicated below.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Attention: Johna Hurl, Monument Manager, 3801 Pegasus Drive, Bakersfield, CA 93308. Phone at (661) 391–6093 or e-mail: *jhurl@blm.gov*.

Dated: June 19, 2007.

Johna Hurl,

Manager, Carrizo Plain National Monument.

[FR Doc. E7–12259 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–060–01–1020–PG]

Notice of Public Meeting; Central Montana Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Central Montana Resource Advisory Council (RAC) will meet as indicated below.

DATES: The meeting will be held July 18 and 19, 2007, at the Bureau of Land Management's Lewistown Field Office, 920 NE. Main Street, in Lewistown, Montana. The July 18 session will begin at 10 a.m. with a 30-minute public comment period. Following the public comment period, the group will depart for a field trip in the Judith Mountains to discuss travel planning. This meeting is scheduled to adjourn at 5:30 p.m. The July 19 meeting will begin at 8 a.m. with a 30-minute public comment Period and is scheduled to adjourn at 3 p.m.

SUPPLEMENTARY INFORMATION: This 15-member council advises the Secretary of the Interior on a variety of management issues associated with public land management in Montana. During these meetings the council will discuss/act upon:

Travel planning in the Judith-Moccasin Mountains;
The minutes of their preceding meeting;
Field managers' updates;
The oil and gas program, activities and issues;
The Bear Paw South Environmental Impact Statement;
The format for U.S. Forest Service fee proposals;
Law enforcement issues;
A BLM grazing rule update;
An open discussion; and
Administrative details (next meeting agenda, location, etc.).

All RAC meetings are open to the public. The public may present written comments to the RAC. Each formal RAC meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

FOR FURTHER INFORMATON CONTACT: June Bailey, Lewistown Field Manager, Lewistown Field Office, P.O. Box 1160, Lewistown, Montana 59457, 406–538–1900.

Dated: June 15, 2007.

Scott Haight,

Acting Lewistown Field Manager.

[FR Doc. E7–12226 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–330–07–7122 FR; AZA–33570]

Notice of Realty Action; Recreation and Public Purposes Act Classification; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action.

SUMMARY: The Bureau of Land Management (BLM) has examined and found suitable for classification to La Paz County for conveyance under the provisions of the Recreation and Public Purposes Act, a 20-acre parcel of public land, located in La Paz County, Arizona. The County plans to construct and operate a wastewater treatment plant on the site to serve communities in the Colorado River area.

DATES: Interested parties may submit written comments at the address stated below, postmarked no later than August 9, 2007.

ADDRESSES: Interested parties may submit written comments to the Field Manager, BLM Lake Havasu Field Office, 2610 Sweetwater Avenue, Lake Havasu City, Arizona 86406. Detailed information concerning this action, including but not limited to documentation related to compliance with applicable environmental and cultural resource laws, is available for review at the above address during

regular business hours (8 a.m. to 4:30 p.m.), Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Cory Bodman, Realty Specialist, BLM Lake Havasu Field Office, telephone (928) 505–1215.

SUPPLEMENTARY INFORMATION: The following described public land is proposed for classification under Section 7 of the Taylor Grazing Act, 43 U.S.C. 315f, and Executive Order No. 6910, and classification and conveyance under the provisions of the Recreation and Public Purposes (R&PP) Act, as amended (43 U.S.C. 869 *et seq.*), for the purpose of placement of a wastewater treatment plant.

Land proposed for this classification and disposal action is:

Gila and Salt River Meridian, La Paz County, Arizona

T. 10 N., R. 19 W.,
Sec. 26: E½SE¼SW¼.

The land described contains approximately 20 acres in La Paz County.

Requirements of the Arizona Department of Environmental Quality indicate a wastewater treatment plant is needed to serve the growing Colorado River area communities. In accordance with the R&PP Act, as amended, La Paz County has filed an R&PP petition/application and plan of development to the BLM Lake Havasu Field Office in which it proposes to develop a wastewater treatment plant on the above described public land. The land is not needed for federal purposes. Conveyance pursuant to the R&PP Act is consistent with the Lake Havasu Field Office Resource Management Plan, dated May 10, 2007, and would be in the public interest. Public meetings were held in conjunction with the planning process, and included discussions of the proposed classification and disposal of the above described public land under the R&PP Act.

The conveyance, when issued, will be subject to the following terms, conditions, and reservations:

1. Provisions of the R&PP Act and to all applicable regulations, including but not limited to regulations stated in 43 CFR Part 2470, and policy and guidance of the Secretary of the Interior.

2. Reservation of a right-of-way to the United States for ditches and canals pursuant to the Act of August 30, 1890, 43 U.S.C. 945.

3. All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove the minerals under applicable laws and regulations established by the Secretary of the Interior, including all necessary access and exit rights.

4. No portion of the land patented shall revert back to the United States under any circumstances if such portion has been used for solid waste disposal or for any other purpose that the authorized officer determines may result in the disposal, placement, or release of any hazardous substance. In addition the patentee shall comply with all Federal state laws applicable to the disposal, placement, or release of hazardous substances (substances as defined in 40 CFR Part 302) and indemnify the United States against any legal liability or future costs that may arise out of any violation of such law.

5. All valid existing rights of record, including those documented on the official public land records at the time of patent issuance.

6. Pursuant to the requirements established by section 120(h) of the Comprehensive Environmental Response, Compensation and Liability Act, (42 U.S.C 9620(h)) (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1988, (100 Stat. 1670) notice is hereby given that the above-described land has been examined and no evidence was found to indicate that any hazardous substances had been stored for one year or more, nor had any hazardous substances been disposed of or released on the subject property.

7. The purchaser/patentee, by accepting a patent, covenants and agrees to indemnity, defend, and hold the United States harmless from any costs, damages, claims, causes of action, penalties, fines, liabilities, and judgments of any kind or nature arising from the past, present, and future acts or omissions of the patentees or their employees, agents, contractors, lessees, or any third party, arising out of or in connection with the patentee's use, occupancy, or operations on the patented real property. This indemnification and hold harmless agreement includes, but is not limited to, acts and omissions of the patentee and their employees, agents, contractors, lessees, or any third party, arising out of or in connection with the use, and/or occupancy, of the patented real property which has already resulted or does hereafter result in: (1) Violations of Federal, State and local laws and regulations that are now or may in the future become, applicable to the real property; (2) Judgments, claims or demands of any kind assessed against the United States; (3) Costs, expenses or damages of any kind incurred by the United States; (4) Releases or threatened releases of solid or hazardous waste(s), and/or hazardous substances(s), as defined by Federal and State environmental laws, off, on, into or under land, property and other interests of the United States; (5) Activities by which solid waste or hazardous substances(s) or waste, as defined by Federal and State environmental laws, are generated, released, stored, used or otherwise disposed of on the patented real property, and any cleanup response, remedial action or other actions related in any manner to said solid or hazardous substances(s) or waste(s); or (6) natural resource damages as defined by Federal and State law. This covenant shall be construed as running with the parcel of land patented or otherwise conveyed by the United States, and may be enforced by the United States in a court of competent jurisdiction.

Upon publication of this notice in the **Federal Register**, the land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for conveyance under the R&PP Act, and leasing under the mineral leasing laws.

Interested parties may submit written comments on the proposed conveyance or classification of the land to the Field Manager, Lake Havasu Field Office, at the address stated above in this notice. Comments must be postmarked no later than August 9, 2007.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Classification Comments: Interested parties may submit written comments, postmarked no later than August 9, 2007 involving the suitability of the land for conveyance for the wastewater treatment plant. Comments on the classification are limited to whether the land is physically suited for the wastewater treatment plant, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments: Interested parties may submit written comments no later than August 9, 2007 regarding the specific use proposed in the application and plan of development, whether the BLM followed proper

administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for the wastewater treatment plant. Any adverse comments will be reviewed by the BLM State Director, who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, the classification will become effective 60 days after June 25, 2007. The land will not be offered for conveyance until after the classification becomes effective.

(Authority: 43 CFR 2741.5)

Dated: April 30, 2007.

Timothy Z. Smith,

Field Manager.

[FR Doc. E7–12263 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–040–07–1430–ES; UTU–82068, UTU–82980]

Notice of Realty Action: Recreation and Public Purposes Act Classification of Public Lands in Iron County, UT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The Bureau of Land Management (BLM) has examined and found suitable for classification for lease or conveyance under the provisions of the Recreation and Public Purposes (R&PP) Act as amended (43 U.S.C. 869, *et seq.*) 10 acres of public lands in Iron County, Utah. The Town of Kannaraville proposes to use the lands as a solid waste transfer station (2.47 acres), and a public baseball park (7.53 acres).

DATES: Interested parties may submit written comments regarding the proposed lease or conveyance or classification of the lands until August 9, 2007.

ADDRESSES: Send written comments to the Cedar City Field Manager, Bureau of Land Management, Cedar City Field Office, 176 East D.L. Sargent Drive, Cedar City, Utah 84720–9337.

FOR FURTHER INFORMATION CONTACT: Randy M. Trujillo, Associate Field Office Manager, Bureau of Land Management, Cedar City Field Office, (435) 865–3080.

SUPPLEMENTARY INFORMATION: The following described public land in Iron County, Utah has been examined and found suitable for classification for conveyance as a solid waste transfer station site (UTU–82068) under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*):

Salt Lake Meridian, Utah

T. 38 S., R. 12 W.
Sec. 34, lot 12, containing 2.47 acres.

The following described public land in Iron County, Utah has been examined and found suitable for classification for lease or conveyance as a public park (UTU–82980) under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*):

Salt Lake Meridian, Utah

T. 38 S., R. 12 W.
Sec. 34, lot 13 (portion), containing 7.53 acres.

The 7.53 acres are to be re-described as lot 16 upon approval of a supplemental survey plat.

The above described 10 acres of public lands are not required for any Federal purpose. Lease or conveyance of the public lands for the stated purposes is in conformance with the BLM Cedar Beaver Garfield Antimony Resource Management Plan (RMP) approved October 1, 1986, as amended September 23, 1997. The proposed conveyance of 2.47 acres and the lease and conveyance of 7.53 acres is in conformance with the RMP because it meets Criterion No. 1 of the RMP, as amended: ''is in the public interest and accommodates the needs of State, local or private entities, including needs for the economy, community growth and expansion and is in accordance with other land use goals and objectives and RMP decisions''.

The lease/conveyances, when issued, will be subject to the provisions of the R&PP Act and applicable regulations of the Secretary of the Interior.

The conveyance (Federal land patent) of 2.47 acres for solid waste transfer station site (BLM Serial No. UTU–82068) will be subject to the following terms and conditions:

Excepting and reserving to the United States:

1. A right-of-way for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. All minerals, together with the right to prospect for, mine, and remove such deposits from the lands under applicable law and such regulations as the Secretary of the Interior may prescribe.

The patent will be subject to:

1. All valid existing rights of record.

2. The patentee shall comply with approved plans of development and management.

3. The patentee warrants that it will indemnify and hold the United States harmless against any liability that may arise out of any violation of Federal or State law in connection with the use of the lands.

4. Title shall revert to the United States upon a finding, after notice and opportunity for a hearing, that the patentee has not substantially developed the lands in accordance with the approved plan of development on or before the date five years after the date of conveyance. No portion of the land shall under any circumstance revert to the United States if any such portion has been used for solid waste disposal or solid waste transfer station operations, or for any other purpose which may result in the disposal, placement, or release of any hazardous substance.

5. If, at any time, the patentee transfers to another party ownership of any portion of the land not used for the purposes specified in the application and approved plan of development, the patentee shall pay the Bureau of Land Management the fair market value, as determined by the authorized officer, of the transferred portion as of the date of transfer, including the value of any improvements thereon.

6. The above described land has been conveyed for utilization as a solid waste transfer station site. Upon closure, the site may contain small quantities of commercial and household waste as determined in the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901), and defined in 40 CFR 261.4 and 261.5. Although there is no indication that these materials pose any significant risk to human health or the environment, future land uses should be limited to those which do not penetrate surface soils or any liner left in place unless excavation is conducted subject to applicable State and Federal requirements.

The lease or conveyance of 7.53 acres for a public baseball park (BLM Serial No. UTU–82980) will be subject to the following terms and conditions:

Excepting and reserving to the United States:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. All minerals, together with the right to prospect for, mine, and remove such deposits from the lands under applicable law and such regulations as the Secretary of the Interior may prescribe.

The lease/patent of 7.53 acres will be subject to:

1. All valid existing rights of record.

2. Compliance with approved plans of development and management.

Detailed information concerning these actions is available for review in the office of the BLM, Cedar City Field Office, at the address listed above.

On June 25, 2007, the above described lands are segregated from all forms of appropriation under the public land laws, including the general mining laws, except for lease or conveyance under the R&PP Act, leasing under mineral leasing laws, and disposals under the mineral material disposal laws.

Classification Comments: Interested parties may submit comments involving the suitability of the lands for a solid waste transfer station site and public park purposes. Comments on the classification are restricted to whether the lands are physically suited for the proposal, whether the uses will maximize the future use or uses of the land, whether the uses are consistent with local planning and zoning, or whether the uses are consistent with State and Federal programs.

Application Comments: Interested parties may submit comments regarding the specific uses proposed in the applications and plans of development, whether the BLM followed proper administrative procedures in reaching its decision, or any other factor not directly related to the suitability of the land for the stated uses. Application comments should be specific to the proposed solid waste transfer station site (BLM Serial No. UTU–82068) or the proposed public park (BLM Serial No. UTU–82980).

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The State Director who may sustain, vacate, or modify this realty action will review any adverse comments. In the absence of any adverse comments, this classification action will become the final determination of the Department of the Interior and become effective on August 24, 2007. The lands will not be available for lease or conveyance until after the classification becomes effective.

(Authority: 43 CFR 2400, 2741 and 2912)

Dated: April 18, 2007.

Todd S. Christensen,

Field Office Manager, Cedar City, Utah.

[FR Doc. E7–12268 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–966–1910–BJ–4600; Group No. 30, Virginia]

Eastern States: Filing of Plat of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plat of survey; Virginia.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM–Eastern States, Springfield, Virginia, 30 calendar days from the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153. Attn: Cadastral Survey.

SUPPLEMENTARY INFORMATION: This survey was requested by the National Park Service.

The lands we surveyed are:

A portion of the boundary of the George Washington Memorial Parkway, Fairfax County, Virginia.

The plat of survey represents the dependent resurvey of a portion of the boundary of the George Washington Parkway and was approved June 1, 2007. It will be available to the public as a matter of information.

If BLM receives a protest against this survey, as shown on the plat, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plat until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: June 6, 2007.

Jerry L. Wahl,

Chief Cadastral Surveyor.

[FR Doc. E7–12062 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of an extension of an information collection (1010–0149).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), MMS is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements in the regulations under 30 CFR 250, Subpart I, Platforms and Structures.

DATES: Submit written comments by August 24, 2007.

ADDRESSES: You may submit comments by any of the following methods listed below. Please use the Information Collection Number 1010–0149 as an identifier in your message.

- E-mail MMS at *rules.comments@mms.gov.* Identify with Information Collection Number 1010–0149 in the subject line.
- Fax: 703–787–1093. Identify with Information Collection Number 1010–0149.
- Mail or hand-carry comments to the Department of the Interior; Minerals Management Service; Attention: Cheryl Blundon; 381 Elden Street, MS–4024; Herndon, Virginia 20170–4817. Please reference ''Information Collection 1010–0149'' in your comments.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch at (703) 787–1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the regulation that requires the subject collection of information.

SUPPLEMENTARY INFORMATION:

Title: 30 CFR Part 250, Subpart I, Platforms and Structures.

OMB Control Number: 1010–0149.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior (Secretary) to prescribe rules and regulations to administer leasing of the OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to

balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition.

Section 43 U.S.C. 1356 requires the issuance of ''* * * regulations which require that any vessel, rig, platform, or other vehicle or structure * * * (2) which is used for activities pursuant to this subchapter, comply * * * with such minimum standards of design, construction, alteration, and repair as the Secretary * * * establishes * * *.'' Section 43 U.S.C. 1332(6) also states, ''operations in the [O]uter Continental Shelf should be conducted in a safe manner * * * to prevent or minimize the likelihood of * * * physical obstruction to other users of the water or subsoil and seabed, or other occurrences which may cause damage to the environment or to property, or endanger life or health.'' These authorities and responsibilities are among those delegated to the Minerals Management Service (MMS) to ensure that operations in the OCS will meet statutory requirements; provide for safety and protection of the environment; and result in diligent exploration, development, and production of OCS leases. This information collection request addresses the regulations at 30 CFR Part 250, Subpart I, Platforms and Structures, and the associated supplementary notices to lessees and operators (NTLs) intended to provide clarification, description, or explanation of these regulations.

MMS uses the information submitted under Subpart I to determine the structural integrity of all offshore platforms and floating production facilities and to ensure that such integrity will be maintained throughout the useful life of these structures. We use the information to ascertain that the fixed and floating platforms and structures are structurally sound and safe for their intended use to ensure safety of personnel and pollution prevention. More specifically, we use the information to:

- Review data concerning damage to a platform to assess the adequacy of proposed repairs.
- Review plans for platform construction (construction is divided into three phases—design, fabrication, and installation) to ensure the structural integrity of the platform.
- Review verification plans and reports for unique platforms to ensure that all nonstandard situations are given proper consideration during the design, fabrication, and installation phases of platform construction.
- Review platform design, fabrication, and installation records to ensure that the platform is constructed according to approved plans.
- Review inspection reports to ensure that platform integrity is maintained for the life of the platform.

We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2) and under regulations at 30 CFR 250.197, ''Data and information to be made available to the public or for limited inspection.'' No items of a sensitive nature are collected. Responses are mandatory.

Frequency: On occasion, annually.

Estimated Number and Description of Respondents: There are approximately 136 respondents (Federal oil and gas OCS lessees and their CVAs or other third-party reviewers of production facilities).

Estimated Reporting and Recordkeeping ''Hour'' Burden: The currently approved annual reporting burden for this collection is 42,500 hours. The following chart details the individual components and respective hour burden estimates of this ICR. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

Citation 30 CFR 250 subpart I and related NTLs	Reporting or recordkeeping requirement	Hour/fee burden
900(b), (c), (e); 901(b), (c); 902; 903; 905; 906; 909; 910(c), (d); 911(c), (f); 912; 913.	Submit application, along with reports/surveys and relevant data, to install new platform or floating production facility or conversion of existing platform for new purpose or significant changes to approved applications, including use of alternative codes, rules, or standards; and Platform Verification Program (PVP) plan for design, fabrication and installation of new, fixed, bottom-founded, pile-supported, or concrete-gravity platforms and new floating platforms. Consult as required with MMS and/or USCG. Re/Submit application for major modification(s)/repairs to any platform and related requirements.	30 hours. $19,900 for PVP. $2,850 for fixed structure. $1,450 for caisson/well protector. $3,400 for modifications.
900(b)(5)	Submit application for conversion of the use of an existing mobile offshore drilling unit.	24 hours.
900(c)	Notify MMS within 24 hours of damage and emergency repairs and request approval of repairs.	16 hours.
901(a)(6), (a)(7), (a)(8); NTLs	Submit CVA documentation under API RP 2RD, API RP 2SK, and API RP 2SM.	100 hours.
901(a)(10); NTLs	Submit hazards analysis documentation under API RP 14J	600 hours.
903*	Record original and relevant material test results of all primary structural materials; retain records during all stages of construction. Compile, retain, and provide location/make available to MMS for the functional life of platform, the as-built drawings, design assumptions/analyses, summary of nondestructive examination records, inspection results, and records of repair not covered elsewhere.	100 hours.
911(d); 914	Submit nomination and qualification statement for CVA	16 hours.
916(c)	Submit interim and final CVA reports and recommendations on design phase.	200 hours.
917(a), (c)	Submit interim and final CVA reports and recommendations on fabrication phase, including notice of fabrication procedure changes or design specification modifications.	100 hours.
918(c)	Submit interim and final CVA reports and recommendations on installation phase.	60 hours.

Citation 30 CFR 250 subpart I and related NTLs	Reporting or recordkeeping requirement	Hour/fee burden
919(a)	Develop in-service inspection plan and keep on file	45 hours.
919(b)	Submit annual (November 1 of each year) report on inspection of platforms or floating production facilities, including summary of testing results.	80 hours.
900 thru 921	General departure and alternative compliance requests not specifically covered elsewhere in Subpart I regulations.	8 hours.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: The currently approved ''non-hour cost'' burden for this information collection is a total of $752,606. This represents four cost burdens for filing fees associated with submitting applications for platforms and structures. See the table above for specific details.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *''. Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Agencies must also estimate the ''non-hour cost'' burdens to respondents or recordkeepers resulting from the collection of information. Therefore, if you have costs to generate, maintain, and disclose this information, you should comment and provide your total capital and startup cost components or annual operation, maintenance, and purchase of service components. You should describe the methods you use to estimate major cost factors, including system and technology acquisition, expected useful life of capital equipment, discount rate(s), and the period over which you incur costs. Capital and startup costs include, among other items, computers and software you purchase to prepare for collecting information, monitoring, and record storage facilities. You should not include estimates for equipment or services purchased: (i) Before October 1, 1995; (ii) to comply with requirements not associated with the information collection; (iii) for reasons other than to provide information or keep records for the Government; or (iv) as part of customary and usual business or private practices.

We will summarize written responses to this notice and address them in our submission for OMB approval. As a result of your comments, we will make any necessary adjustments to the burden in our submission to OMB.

Public Comment Procedures: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information-may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

MMS Information Collection Clearance Officer: Arlene Bajusz (202) 208–7744.

Dated: June 18, 2007.

E.P. Danenberger,

Chief, Office of Offshore Regulatory Programs.

[FR Doc. E7–12171 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

National Park Service

30-Day Notice of Submission to the Office of Management and Budget; Opportunity for Public Comment

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice and request for comments.

SUMMARY: Under provisions of the Paperwork Reduction Act of 1995 and 5 CFR Part 1320, Reporting and Recordkeeping Requirements, the National Park Service (NPS) invites comments on an extension of a currently approved collection of information (OMB Control Number 1024–0233).

DATES: Public comments on the Information Collection Request (ICR) will be accepted on or before July 25, 2007.

ADDRESSES: You may submit comments directly to the Desk Officer for the Department of the Interior (OMB Number 1024–0233), Office of Information and Regulatory Affairs, OMB, by fax at 202/395–6566, or by electronic mail at *OIRA_DOCKET@omb.eop.gov.* Please also send a copy of your comments to Ms. Jo A. Pendry, Concession Program Manager, National Park Service, 1849 C Street, NW. (2410), Washington, DC 20240, or electronically to *jo_pendry@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Jo A. Pendry, phone: 202–513–7156; fax: 202–371–2090; or at the address above. You are entitled to the entire ICR package free-of-charge.

Comments Received on the 60-day ***Federal Register*** *Notice:* The NPS published the 60-day **Federal Register** Notice to solicit comments on this ICR on March 30, 2007, on page 15158. There were no public comments received as a result of publishing this 60-Day **Federal Register** Notice.

SUPPLEMENTARY INFORMATION:

Title: National Park Service Leasing Program—36 CFR part 18.

Form Number(s): None.

OMB Control Number: 1024–0233.

Expiration Date of Approval: June 30, 2007.

Type of Request: Extension of a currently approved information collection.

Description of Need: The information is being collected to meet the requirements of Section 802 of the NPS Concessions Management Improvement Act of 1998, concerning the legislative authority, policies, and requirements for the solicitation, award, and administration of NPS leases for property located within area of the national park system. The obligation to respond is required to obtain or retain benefits.

Frequency of Collection: On occasion.

Description of Respondents: Persons or entities seeking a leasing opportunity with the National Park Service.

Estimated average number of respondents: 627 per year.

Estimated average number of responses: 627 per year.

Estimated average time burden per response: 7 hours.

Frequency of response: Once per respondent.

Estimated total annual reporting burden: 4,392 hours.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 18, 2007.

Leonard E. Stowe,

NPS, Information Collection Clearance Officer.

[FR Doc. 07–3089 Filed 6–22–07; 8:45 am]

BILLING CODE 4312–53–M

DEPARTMENT OF THE INTERIOR

National Park Service

30-Day Notice of Submission to the Office of Management and Budget; Opportunity for Public Comment

AGENCY: The Department of the Interior, National Park Service.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3507) and 5 CFR part 1320, Reporting and Recordkeeping Requirements, the National Park Service (NPS) invites public comments on a revision of a currently approved collection of information (OMB #1024–0021).

DATES: Public comments on the Information Collection Request (ICR) will be accepted on or before July 25, 2007.

ADDRESSES: You may submit comments directly to the Desk Officer for the Department of the Interior (OMB # 1024–0021), Office of Information and Regulatory Affairs, OMB, by fax at 202/395–6566, or by electronic mail at *oria_docket@omb.eop.gov*. Please also send a copy of your comments to Richard E. Merryman, NPS, National Capital Region (Room 128), 1100 Ohio Drive, SW., Washington, DC 20242, or by fax at 202/401–2430, or by electronic mail at *rick_merryman@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Richard E. Merryman, National Capital Region, 1100 Ohio Dr., Room 128, SW., Washington, DC 20242, or by phone at 202/619–7225, or by fax at 202/401–2430, or by e-mail at *rick_merryman@nps.gov.* You are entitled to a copy of the entire ICR package free of charge.

Comments Received on the 60-Day ***Federal Register*** Notice: The NPS published at 60-Day Notice to solicit public comments on this ICR in the **Federal Register** on March 9, 2007 (Vol. 72, pages 10554–10555). The comment period closed on May 7, 2007. No comments were received.

SUPPLEMENTARY INFORMATION:

Title: National Capital Region Application for Public Gathering, 36 CFR 7.96(g).

Form Number: None.

OMB Number: 1024–0021.

Expiration Date: June 30, 2007.

Type of Request: Revision of a currently approved collection of information.

Description of Need: The information collection responds to the statutory requirement (36 CFR 7.96(g)) that the NPS preserve park resources and regulate the use of units of the National Park System. The information to be collected identifies: (1) Those individuals and/or organizations that wish to conduct a public gathering on NPS property in the National Capital Region, (2) the logistics of a proposed demonstration or special event that aid the NPS in regulating activities to insure that they are consistent with the NPS mission, (3) potential civil disobedience and traffic control issues for the assignment of United States Park Police personnel, and (4) circumstances which may warrant a bond to be assigned to the event for the purpose of covering potential cost to repair damage caused by the event.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Frequency of Collection. On occasion.

Description of Respondents: Individuals or organizations that wish to conduct a special event or demonstration on NPS properties within the National Capital Region that lie within the geographical limits set forth in 36 CFR 7.96(g).

Estimated average number of annual respondents: 2500 per year.

Estimated average number of responses: 2500 per year.

Estimated average time burden per respondent: 30 minutes.

Frequency of response: Once per respondent.

Estimated total annual reporting burden: 1,250 hours per year.

Dated: June 18, 2007.

Leonard E. Stowe,

NPS, Information Collection Clearance Officer.

[FR Doc. 07–3092 Filed 6–22–07; 8:45 am]

BILLING CODE 4312–JK–M

DEPARTMENT OF THE INTERIOR

National Park Service

30-Day Notice of Submission to the Office of Management and Budget; Opportunity for Public Comment

AGENCY: The Department of the Interior; National Park Service.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3507) and 5 CFR part 1320, Reporting and Record keeping Requirements, the National Park Service (NPS) invites public comments on an extension of a currently approved collection of information (OMB No. 1024–0245).

DATES: Public comments on this Information Collection Request (ICR)

will be accepted on or before July 25, 2007.

ADDRESSES: You may submit comments directly to the Desk Officer for the Department of the Interior (OMB number 1024–0245), Office of Information and Regulatory Affairs, OMB, by fax at 202/395–6566, or by electronic mail at *oira_docket@omb.eop.gov.* Please also send a copy of your comments to Lieutenant Dennis Maroney, Assistant Commander, Human Resource Office, United States Park Police, 1100 Ohio Drive, SW., Washington, DC 20024, via fax at 202/619–7479, or via e-mail at *Dennis_Maroney@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Lieutenant Dennis Maroney, Assistant Commander Human Resources Office, United States Park Police (USPP), 1100 Ohio Drive, SW., Washington, DC 20024, via fax at 202/619–7479, or via e-mail at *Dennis_Maroney@nps.gov,* or via telephone at 202/619–7413. You are entitled to a copy of the entire ICR package free-of-charge.

Comments Received on the 60-Day ***Federal Register*** *Notice:* The NPS published the 60-Day **Federal Register** Notice to solicit comments on this ICR on April 16, 2007 (Vol. 72, pages 19019–19020). There were no public comments received as a result of publishing this 60-Day **Federal Register** Notice.

SUPPLEMENTARY INFORMATION:

Title: United States Park Police Personal History Statements Questionnaire.

Form Number: USPP Form 1.

OMB Number: 1024–0245.

Expiration Date: June 20, 2007.

Type of Request: Extension of a currently approved information collection.

Description of need: Title 5, Code of Federal Regulations, section 5.2; Title 5, United States Code, sections 1302, 1304, and 3301; sections 8(b), 8(c), and 9(c) of Executive Order 10450; Title 42, United States Code, section 2455; and Title 22, United States Code, sections 1434 and 2585, established investigative standards for all United States Government civilian and military personnel. The position of a Police Officer in the USPP is critical sensitive. The purpose of the USPP Personal History Statement Questionnaire is to collect detailed information that will be used principally as a basis for an investigation to determine suitable applicants for the position of a USPP Officer. This information has an impact on individuals that apply to the position of a USPP Officer. The NPS uses the information that is collected to hire adequately screened applicants for the position of a USPP Officer. The obligation to respond is required to obtain or retain benefits.

Comments are invited on: (1) the practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Frequency of Collection: Annually.

Description of Respondents: Individuals seeking employment to the position of a United States Park Police Officer.

Estimated average number of respondents: 600 per year.

Estimated average number of responses: 600 per year.

Frequency of response: Once per respondent.

Estimated average time burden per respondent: 8 hours per respondent.

Estimated total annual reporting burden: 4,800 hours per year.

Dated: June 18, 2007.

Leonard E. Stowe,

NPS, Information Collection Clearance Officer.

[FR Doc. 07–3093 Filed 06–22–07; 8:45 am]

BILLING CODE 4312–JU–M

DEPARTMENT OF THE INTERIOR

National Park Service

30 Day Notice of Submission to the Office of Management and Budget; Opportunity for Public Comment

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice and request for comments.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3507) and 5 CFR part 1320, Reporting and Record Keeping Requirements, the National Park Service (NPS) invites public comments on an extension of a currently approved collection of information (OMB number 1024–0022).

DATES: Public comments on this Information Collection Request (ICR) will be accepted on or before July 25, 2007.

ADDRESSES: You may submit comments directly to the Desk Officer for the Department of the Interior (OMB number 1024–0022), Office of Information and Regulatory Affairs, OMB, by fax at 202/395–6566, or by electronic mail at *oira_docket@omb.eop.gov.* Please also send a copy of your comments to Lee Dickinson, Special Park Uses Program Manager, NPS, 1849 C St., NW., (2460), Washington, DC 20240, or electronically at *Lee_Dickinson@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Lee Dickinson, Special Park Uses Program Manager, NPS, 1849 C St., NW. (2460), Washington, DC 20240, or via phone at 202/513–7092, or via e-mail at *Lee_Dickinson@nps.gov.* Copies of this form may be obtained from the Internet at *http://www.nps.gov/policy/DOrders/BUP.pdf* or by contacting Lee at the address above. You are entitled to a copy of the entire ICR package free of charge.

Comments received on the 60-day ***Federal Register*** *Notice:* The NPS published a 60-Day Notice to solicit public comments on this ICR in the **Federal Register** on March 8, 2007 (Vol. 72, page 10555). The comment period closed on May 7, 2007. No comments were received.

SUPPLEMENTARY INFORMATION:

Title: Backcountry Use Permit (36 CFR 1.5, 1.6, and 2.10).

Form Number: 10–404A.

OMB Number: 1024–0022.

Expiration Date: 6/30/07.

Type of Request: Extension of a currently approved collection.

Description of Need: In 1976, the NPS initiated a backcountry registration system in accordance with the regulations found at 36 CFR 1.5, 1.6 and 2.10. The objective of the backcountry use permit system is to provide users access to backcountry areas of national parks with continuing opportunities for solitude, while enhancing resource protection and providing a means of disseminating public safety messages regarding backcountry travel.

NPS backcountry program managers, by designating access routes and overnight camping locations, can redistribute campers in response to user impact, high fire danger, flood or wind hazard, bear activity, or other situations that may temporarily close a portion of the backcountry. The NPS may also use the permit system as a means of

ensuring that each backcountry user receives up-to-date information on backcountry sanitation procedures, food storage, wildlife activity, trail conditions, and weather projections so that concerns for visitor safety are met.

The Backcountry Use Permit is an extension of the NPS statutory authority responsibility to protect the park areas it administers and to manage the public use thereof (16 U.S.C. Sections 1 and 3). NPS regulations codified in 36 CFR Parts 1 through 7, 12 and 13, are designed to implement statutory mandates that provide for resource protection and public enjoyment. The Backcountry Use Permit is the primary form used to provide access into NPS backcountry areas including those areas that require a reservation to enter where use limits are imposed in accordance with other NPS regulations. Such permitting enhances the ability of the NPS to education users on potential hazards, search and rescue efforts, and resource protection.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Frequency of collection: On occasion.

Description of Respondents: Individuals wishing to use backcountry areas within national parks.

Estimated average number of respondents: 285,000 per year.

Estimated average number of responses: 285,000 per year.

Estimated average time burden per respondent: 5 minutes per respondent.

Frequency of response: 1 time per respondent.

Estimated total annual reporting burden: 23,750 hours per year.

Dated: June 18, 2007.

Leonard E. Stowe,

NPS, Information Collection Clearance Officer.

[FR Doc. 07–3094 Filed 6–22–07; 8:45 am]

BILLING CODE 4312–53–M

DEPARTMENT OF THE INTERIOR

National Park Service

30-Day Notice of Submission of Study Package to the Office of Management and Budget; Opportunity for Public Comment

AGENCY: Department of the Interior, National Park Service.

ACTION: Notice and request for comments.

SUMMARY: Under provisions of the Paperwork Reduction Act of 1995 [44 U.S.C. 3507(a)(1)(D)] and 5 CFR Part 1320, Reporting and Record keeping Requirements, the National Park Service (NPS) invites public comments on a revision of a currently approved collection of information (OMB number 1024–0236).

DATES: Public comments on this Information Collection Request (ICR) will be accepted on or before July 25, 2007.

ADDRESSES: Youb may submit comments directly to the Desk Officer for the Department of the Interior (OMB number 1024–0236), Office of Information and Regulatory Affairs, OMB, by fax at 202/395–6566 or by electronic mail at *oira_docket@omb.eop.gov.* Please also send a copy of your comments to Dr. John G. Dennis, Natural Resources (MIB 3130), NPS, 1849 C Street, NW., Washington, DC 20240, or electronically at *WASO_NRSS_researchcoll@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. John G. Dennis, Natural Resources (MIB 3130), NPS, 1849 C Street, NW., Washington, DC 20240; or via phone at 202/513–7174; or via fax at 202/371–2131, or via e-mail at *WASO_NRSS_researchcoll@nps.gov.* You are entitled to a copy of the entire ICR package free of charge.

Comments Received on the 60-Day ***Federal Register*** *Notice:* The NPS published the 60-Day **Federal Register** Notice to solicit public comments on this ICR on March 8, 2007 (Vol. 72, pages 10553–10554). NPS also contacted by e-mail 3,588 non-Federal and Federal permittees and permit applicants who were active in calendar years 2006 and 2007, posted on the RPRS Web site notice of the availability of this review opportunity, and sent an internal memorandum to the NPS Natural Resource Advisory Group to solicit comments from the members of that group.

The NPS received 13 responses from the public in response to the 60-day **Federal Register** Notice and subsequent e-mail messages requesting comments. These responses provided a diversity of thoughts, including (1) The requested information and time needed to fill out the forms are reasonable; (2) the on-line application process is efficient and straightforward; (3) the forms and the ability to access on-line and report on-line make the application and compliance process very easy; (4) the park review and decision process is difficult and onerous; (5) too much documentation is required; (6) having each park make its own permit decision is unnecessarily piecemeal, arbitrary, and burdensome; and (7) it is difficult to figure out how to submit ''things''. Five respondents specifically addressed the education application and permit, saying that it would have benefits or offering ideas about what types of education activities should receive specific types of consideration, such as simplifying the application process, how to treat specimen collections, allowing for different treatment for different types of activities, offering the ability to change the program leader without reissuing a permit, and offering a fee waiver for permitted education activities. Several respondents discussed matters outside this request for review, including urging NPS to change its collections ownership procedure and requesting the NPS to issue permits on a Servicewide, rather than park basis.

The NPS found that these comments did not indicate any clear reasons for changing any of the three forms, so the NPS will request to OMB that the three forms be renewed without change. The NPS plans to use the information contained in many of the comments when it develops new guidance material for the Science Education Permit Application, and revises existing guidance material for the Scientific Research and Collecting Permit Application.

Actual NPS and researcher use of the Internet-based system over the past three years has yielded few complaints and has earned a number of kudos. This use also has yielded suggestions from both respondents and government employees for making the information collection forms or software more efficient or more usable. These suggestions have been accumulated and some have been incorporated through ongoing software and technical support

improvements. Such receipt of, and action on, user suggestions, constitutes ongoing consultation with people (applicants and permittees) from whom information is being collected and by whom collected information is being applied (NPS personnel and users of the Investigator's Annual Report site). Should OMB approve the collection of information forms submitted in this extension request, additional software changes will be made to incorporate fully the improvements contained in these forms.

SUPPLEMENTARY INFORMATION:

Title: Research Permit and Reporting System Applications and Reports (36 CFR 2.1 and 2.5).

Bureau Form Number(s): 10–741a, 10–741b, and 10–226.

OMB Number: 1024–0236.

Expiration Date: June 30, 2007.

Type of Request: Revision of a currently approved collection of information.

Description of Need: The NPS regulates scientific research and collecting studies and science education activities inside park boundaries under regulations codified at 36 CFR Part 2, Section 2.5. The NPS issued these regulations pursuant to authority under the NPS Organic Act of 1916 as amended (16 U.S.C. 1 *et seq.*). The NPS administers these regulations to provide for scientific research and collecting and scientific education uses of parks while also protecting park resources and other park uses from adverse impacts that could occur if inappropriate scientific research and collecting studies or science education activities were to be conducted within park boundaries.

The currently approved information collection responds to the statutory requirement that NPS preserve park resources and regulate the use of units of the National Park System. The information currently collected includes: (1) Names and business contact information for people who seek a permit to conduct natural or social science research and collection activities in individual units of the National Park System, (2) what activities they wish to conduct, (3) where they wish to conduct the activities, (4) whether or not they wish to collect specimens as part of the activities they propose to conduct, and (5) for applicants who have received a permit, annual summaries of the actual results of their permitted activities. NPS uses the collected information for managing the use and preservation of park resources and for reporting the status of permitted research and collecting activities. NPS is requesting that OMB approve the current Application for a Scientific Research and Collecting Permit, Application for a Science Education Permit, and Investigator's Annual Report collection of information forms unchanged. The obligation to respond to this collection is required to manage the conduct of scientific research and collecting within national parks.

Comments are invited on: (1) The practical utility of the information being gathered; (2) the accuracy of the burden hour estimate; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden to respondents, including use of automated information collection techniques or other forms of information technology. All comments will become a matter of public record. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Frequency of Response: On occasion.

Description of Respondents: Individual scientific investigators or science educators from other governmental agencies, universities and colleges, schools, research organizations, science education organizations who apply for a permit, and any members of this group who receive a permit; and as a result, must submit the required annual report of accomplishment.

Estimated average number of respondents: 6,500 per year.

Estimated average number of responses: 13,000 per year.

Estimated average time burden per respondent: 6000 responses for Form 10–741a: 1 hour; 500 responses for Form 10–741b: 1 hour, 6500 responses for Form 10–226: 37.5 minutes. Therefore, the total average time burden per respondent is 1.625 hours.

Frequency of response: 2 per respondent.

Estimated total annual reporting burden: 10,563 hours.

Dated: June 20, 2007.

Leonard E. Stowe,

NPS, Information Collection Clearance Officer.

[FR Doc. 07–3095 Filed 6–22–07; 8:45 am]

BILLING CODE 4310–EJ–M

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before June 9, 2007. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by July 10, 2007.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

CALIFORNIA

Tuolumne County

Tuolumne County Courthouse (Boundary Increase), Bounded by N Washington St., W Yaney Ave., N Green St. & W Jackson St., Sonora, 07000695

COLORADO

Larimer County

East Longs Peak Trail—Longs Peak Trail—Keyhole Route—Shelf Trail, (Rocky Mountain National Park MPS) W of CO 7, Allenspark, 07000740

Morgan County

Rankin Presbyterian Church, 420 Clayton St., Brush, 07000696

CONNECTICUT

Hartford County

Trinity Methodist Episcopal Church, 69 Main St., New Britain, 07000697

FLORIDA

Highlands County

Archbold Biological Station at Red Hill, 123 Main Dr., Venus, 07000698

GEORGIA

Muscogee County

Columbus Manufacturing Company, 3201 1st Av., Columbus, 07000699

Walker County

Chickamauga Historic District, Roughly centered on Cove Rd. and bounded by Crescent, Pearl, & 6th Sts. and the Central of Georgia RR, Chickamauga, 07000700

ILLINOIS

Piatt County

Allerton, Robert, Estate, 515 Old Timber Rd., Monticello, 07000701

MISSOURI

Jackson County

Stenzel, R.O. & Company, Warehouse, (Railroad Related Historic Commercial and Industrial Resources in Kansas City, Missouri MPS) 1811 Walnut, Kansas City, 07000702

St. Louis Independent city Harrison School, 4224 Fair Av., St. Louis, 07000703

Holly Place Historic District, 4500 Blk. of Holly Place, St. Louis, 07000704

Plaza Square Apartments Historic District, Bounded by 15th, Olive, 17th & Chestnut Sts., St. Louis, 07000705

TENNESSEE

Hardeman County

Pocahontas School, 22555 TN 57, Pocahontas, 07000706

WASHINGTON

Clallam County

Altair Campground Community Kitchen, (Olympic National Park MPS) Approx. 4 mi. S of U.S. 101, Port Angeles, 07000732

Botten Cabin, (Olympic National Park MPS) 20.9 mi. from Whiskey Bend Trailhead on the Elwha River Trail, Port Angeles, 07000729

Canyon Creek Shelter, (Olympic National Park MPS) Approx. 9 mi. N of the Upper Sol Duc River Trailhead, Port Angeles, 07000712

Dodger Point Fire Lookout, (Olympic National Park MPS) Approx. 13 mi. along Dodger Point Trail starting at the Whiskey Bend Trail Port Angeles, 07000736

Eagle Ranger Station, (Olympic National Park MPS) Approx. 11.6 mi. S of WA 101 on Upper Sol Duc Rd., Port Angeles, 07000713

Elk Lick Lodge, (Olympic National Park MPS) 13 mi. from Whiskey Bend Trailhead on the Elwha River Trail, Port Angeles, 07000734

Elkhorn Guard Station, (Olympic National Park MPS) Approx. 11.5 mi. along Elwha River Trail from the Whiskey Bend Trailhead, Port Angeles, 07000714

Elwha Campground Community Kitchen, (Olympic National Park MPS) 3 mi S of U.S. 101, Port Angeles, 07000735

Elwha Ranger Station, (Olympic National Park MPS) Approx. 3 mi. SE of WA 101 on the Olympic Hot Springs Rd., Port Angeles, 07000716

Fifteen Mile Shelter, (Olympic National Park MPS) Approx. 12.4 mi. from park boundary on N Fork Bogachiel R Trail, Port Angeles, 07000715

Hayes River Fire Cache, (Olympic National Park MPS) Approx. 16.8 mi. up the Elwha River Trail, Port Angeles, 07000738

Humes Ranch Cabin (Boundary Increase), (Olympic National Park MPS) 2.5 mi. from the Whiskey Bend Trailhead, Port Angeles, 07000731

Hyak Shelter, (Olympic National Park MPS) Approx. 15.4 mi. from park boundary on N Fork Bogachiel River Trail, Port Angeles, 07000721

Michael's Cabin, (Olympic National Park MPS) Along Elwha River Trail; approx. 2 mi. from Whiskey Bend Trailhead, Port Angeles, 07000733

North Fork Sol Duc Shelter, (Olympic National Park MPS) Approx. 9.5 mi. from North Fork Sol Duc Trailhead, Port Angeles, 07000725

Olympic National Park Headquarters Historic District, (Olympic National Park MPS) 600 E. Park Ave., Port Angeles, 07000720

Pyramid Peak Aircraft Warning Service Lookout, (Olympic National Park MPS) 3.5 miles up Pyramid Pk. trail at end of Camp David Jr. Rd., Port Angeles, 07000726

Roose, Peter, Homestead, (Olympic National Park MPS) Along Indian Village Trail; approx. 1.5 mi. N of trailhead, Port Angeles, 07000723

Singer's Lake Crescent Tavern, (Olympic National Park MPS) Barnes Point, S. Shore of Lake Crescent, WA 101, Port Angeles, 07000724

Storm King Ranger Station, (Olympic National Park MPS) Barnes Pt., S side of Lake Crescent off U.S. 101, Port Angeles, 07000730

Three Forks Shelter, (Olympic National Park MPS) Approx. 4.5 mi. from the Three Fords Trailhead at Deer Park Campground, Port Angeles, 07000728

Wendel Property, (Olympic National Park MPS) 5 mi. N on East Shore Rd., Port Angeles, 07000739

Grays Harbor County Kestner Homestead, (Olympic National Park MPS) N side of Quinault R., Port Angeles, 07000741

Jefferson County

Enchanted Valley Chalet, (Olympic National Park MPS) 13 mi. upriver from Graves Cr. Trailhead, Port Angeles, 07000737

Graves Creek Ranger Station, (Olympic National Park MPS) Approx. 22 mi. NE of WA 101 on Quinault River Rd., Port Angeles, 07000717

Happy Four Shelter, (Olympic National Park MPS) Approx. 5.4 along Hoh River Trail, Port Angeles, 07000719

North Fork Quinault Ranger Station, (Olympic National Park MPS) Approx. 18 mi. NE of WA 101 on N. Fork Rd. off N. Shore Quinault Rd., Port Angeles, 07000718

Olympus Guard Station, (Olympic National Park MPS) Approx. 9 mi. from Hoh River Trailhead at Hoh Ranger Station, Port Angeles, 07000722

Pelton Creek Shelter, (Olympic National Park MPS) Approx. 15.5 mi. up the Queets River Trail, Port Angeles, 07000727

WISCONSIN

Brown County

North Michigan Street—North Superior Street Historic District, Roughly bounded by Ridgeview Bvd., N Wisconsin, N Huron & George Sts., De Pere, 07000707

Grant County

Bayley Avenue Historic District, 100–400 Bayley Av., 400 Blk. S Court St., 150, 210, 270 Rountree Av. & 65 Mitchell Av., Platteville, 07000708

Division Street Historic District, 200–300 Blk. Division St., 145, 170, 175, 190, 195, 220 S Chestnut St., Platteville, 07000709

West Main Street Historic District, Roughly bounded by N & S Elm, W Pine, N & S Hickory & W Mineral Sts., Platteville, 07000710

Polk County

St. Croix Falls Auditorium, 201 N Washington St, St. Croix Falls, 07000711

[FR Doc. E7–12169 Filed 6–22–07; 8:45 am]

BILLING CODE 4312–51–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (07–050)]

NASA Advisory Council; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council. The agenda for the meeting includes updates from each of the Council committees, including discussion and deliberation of potential recommendations. The Council Committees address NASA interests in the following areas: Aeronautics, Audit and Finance, Space Exploration, Human Capital, Science, and Space Operations.

DATES: Thursday, July 19, 2007, 8 a.m.—4:30 p.m.

ADDRESSES: Marshall Space Flight Center (MSFC), Building 4200, Room P110 (10th floor), Marshall Space Flight Center, AL 35812–0001. (Note that visitors will first need to go to the MSFC Visitor's Center to be gain access.)

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Blackerby, Designated Federal Official, National Aeronautics and Space Administration, Washington, DC, 20546, 202/358–4688.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. All U.S. citizens desiring to attend the NASA Advisory Council Meeting at the Marshall Space Flight Center (MSFC) must provide their full name, company affiliation (if applicable), citizenship, place of birth, and date of birth to the MSFC Security Office no later than the close of business on July 10, 2007. All non-U.S. citizens must submit their name, current address, citizenship, company affiliation (if applicable) to include address, telephone number, and their title, place of birth, date of birth, U.S. visa information to include type, number, and expiration date, U.S. Social Security Number (if applicable),

Permanent Resident Alien card number and expiration date (if applicable), place and date of entry into the U.S., and Passport information to include Country of issue, number, and expiration date to the MSFC Security Office no later than the close of business on July 5, 2007. If the above information is not received by the noted dates, attendees should expect a minimum delay of two (2) hours. All visitors to this meeting will be required to process in through the Redstone/MSFC Joint Visitor Control Center located on Rideout Road, north of Gate 9 prior to entering MSFC. Please provide the appropriate data, via fax 256–544–2101, noting at the top of the page ''Public Admission to the NASA Advisory Council Meeting at MSFC.'' For security questions, please call Becky Hopson at 256–544–4541.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Dated: June 19, 2007.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. E7–12167 Filed 6–22–07; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before July 25, 2007 (Note that the new time period for requesting copies has changed from 45 to 30 days after publication). Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records covered by a proposed schedule. These, too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting the Life Cycle Management Division (NWML) using one of the following means:

Mail: NARA (NWML), 8601 Adelphi Road, College Park, MD 20740–6001.

E-mail: requestschedule@nara.gov.

Fax: 301–837–3698.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

FOR FURTHER INFORMATION CONTACT: Laurence Brewer, Director, Life Cycle Management Division (NWML), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Telephone: 301–837–1539. E-mail: *records.mgt@nara.gov.*

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

Schedules Pending (Note that the new time period for requesting copies has changed from 45 to 30 days after publication):

1. Department of Agriculture, Rural Development (N1–221–06–1, 3 items, 3 temporary items). Inputs, master files, and system documentation relating to an electronic system that manages and processes direct and guaranteed loans and grants for rural electric, telecommunications, water, and environmental programs.

2. Department of the Air Force, Air Force Research Laboratory (N1–AFU–07–1, 13 items, 7 temporary items). Records related to the Air Force Health Study of the health effects of the use of herbicides in Vietnam during the Vietnam War. Included are participant medical files including paper copies, PDF images, X-rays, and dental films; monitor's notes; and queries and other derived datasets. Proposed for permanent retention are the master database, database documentation, hard copy photographs, administrative history files, and a set of technical reports.

3. Department of Defense, National Geospatial-Intelligence Agency (N1–537–03–11, 19 items, 15 temporary items). Geodetic reference files and copies of field survey records, control point descriptions, control photography, planetable drawings, geodetic control

data, geodetic computations, and geographic position files. Proposed for permanent retention are recordkeeping copies of control point descriptions, control photography, and planetable field survey drawings. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

4. Department of Homeland Security, Office of Inspector General (N1–563–07–5, 7 items, 5 temporary items). Case files of routine investigations as well as inputs, master files, and outputs of associated tracking system. Proposed for permanent retention are recordkeeping copies of significant case files and master files of associated tracking system. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium, except for master files and significant case files.

5. Department of Homeland Security, U.S. Coast Guard (N1–26–07–4, 1 item, 1 temporary item). Records documenting training and readiness drills and exercises aboard cutters. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

6. Department of the Interior, U.S. Geological Survey (N1–57–07–1, 11 items, 10 temporary items). Records of the Special Geologic Studies Group, including agreement files, records relating to classification and declassification, project files, and copies of maps used for research and data compilation. Proposed for permanent retention are bibliographies of work products prepared by the group.

7. Department of Justice, Bureau of Prisons (N1–129–07–3, 5 items, 5 temporary items). Inputs, outputs, system documentation and master files of PDF versions of the Regional Director's correspondence. Also included are project reference files. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

8. Department of Justice, Bureau of Prisons (N1–129–07–9, 1 item, 1 temporary item). Year-end roster reports of the Regional Education Administrator. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

9. Department of Justice, Bureau of Prisons (N1–129–07–11, 5 items, 5 temporary items). Files of the Regional Health Services Administrator relating to health care delivery for institutions located within the respective region. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

10. Department of Justice, Federal Bureau of Investigation (N1–65–07–8, 4 items, 2 temporary items). Inputs and outputs of the criminal incident databases of the Domestic Terrorism Analysis Unit. Proposed for permanent retention are data files and system documentation.

11. Department of Justice, Federal Bureau of Investigation (N1–65–07–9, 9 items, 9 temporary items). Inputs, outputs, master file, and system documentation of a database which tracks foreign terrorists.

12. Department of Justice, Federal Bureau of Investigation (N1–65–07–10, 3 items, 3 temporary items). Inputs, master file, and system documentation of databases used for tracking informants.

13. Department of the Navy, Agency-wide (N1–NU–07–3, 1 item, 1 temporary item). Records relating to preliminary law enforcement investigations documenting incidents that do not become full investigations. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

14. Department of the Navy, Agency-wide (N1–NU–07–5, 1 item, 1 temporary item). Non-investigative reports of information related to security of commands or of interest to other law enforcement agencies. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium. Paper recordkeeping copies of these files were previously approved for disposal.

15. Department of State, Bureau of Administration (N1–59–07–3, 3 items, 1 temporary item). Electronic telegrams in the Central Foreign Policy File that are indexed using only subject terms designated as temporary. Records relate to non-substantive administration, business affairs, consular affairs, and operations matters. Proposed for permanent retention are all electronic telegrams covering economic affairs, military and defense affairs, political affairs, social affairs, technology and science, and substantive administration, business services, consular, and operations matters. Also proposed as permanent are all hard copy records in the Central Foreign Policy File and the related electronic indexing information.

16. Department of Transportation, Federal Highway Administration (N1–406–06–2, 6 items, 6 temporary items). Records relating to administrative functions including records of the Contracting Officer's Technical Representative, century date conversion (Y2K) project records, Office of Inspector General hotline complaint/investigative files, and audit case files.

17. Department of Transportation, Federal Railroad Administration (N1–399–07–5, 7 items, 3 temporary items). Program files of the Office of Railroad Development including Amtrak grant administrative records, loan records, and maps generated by the U.S. Geological Survey and Federal Railroad Administration. Proposed for permanent retention are Amtrak Board of Directors records, project case files, aperture cards documenting construction of the Northeast corridor, and national and bilateral agreements. This schedule authorizes the agency to apply the proposed disposition instructions to any recordkeeping medium.

18. National Aeronautics and Space Administration, Agency-wide (N1–255–05–1, 3 items, 2 temporary items). This schedule authorizes the agency to apply the existing disposition instructions to periodic publications, regardless of recordkeeping medium. Included are newsletters, bulletins, and similar publications that contain information relating to facilities, operations, projects and mission development. Proposed for permanent retention is a record copy of each issuance.

19. Tennessee Valley Authority, Board of Directors (N1–142–07–2, 1 item, 1 temporary item). Textual records relating to the planning conducted for board of directors' events. These records include proposed and final agendas, invitation lists, meal orders, cost estimates, and reservations.

20. Tennessee Valley Authority, Board of Directors (N1–142–07–3, 1 item, 1 temporary item). Records relating to X–rays taken of welds performed during construction or maintenance jobs which provide assurance against faulty welds that may cause leaks in boilers or boiler tube sections.

21. U.S. District Courts (N1–21–07–1, 1 item, 1 temporary item). Paper case documents which have been scanned into the Case Management/Electronic Case Filing System from January 1998 to May 2006.

Dated: June 19, 2007.

Michael J. Kurtz,

Assistant Archivist for Records Services—Washington, DC

[FR Doc. E7–12245 Filed 6–22–07; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

Notice of the Availability of the Public Interest Declassification Board (PIDB) By-Laws

AGENCY: National Archives and Records Administration.

ACTION: Notice of the availability of the Public Interest Declassification Board (PIDB) By-Laws.

SUMMARY: The Information Security Oversight Office (ISOO) of the National Archives and Records Administration (NARA) announces the availability of the Public Interest Declassification Board (PIDB) By-Laws. As authorized by Public Law 106–567, and amended by Public Law 108–458, the PIDB is an advisory committee established by Congress and the President to promote the fullest possible public access to a thorough, accurate, and reliable documentary record of significant U.S. national security decisions and activities. The Director of ISOO serves as the PIDB Executive Secretary and the ISOO staff provides staff support for PIDB. Information about the PIDB and the by-laws are available on the PIDB Web site at *http://www.archives.gov/declassification/pidb/*, or you may request a paper copy.

FOR FURTHER INFORMATION CONTACT: To request a paper copy or if you have any questions, please contact Lee Morrison, ISOO, at (202) 357–5039 or send an e-mail to *pidb@nara.gov*.

Dated: June 18, 2007

William J. Bosanko,

Associate Director, Information Security Oversight Office.

[FR Doc. E7–12247 Filed 6–22–07; 8:45 am]

BILLING CODE 7515–01–P

THE NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: The National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given that the following meetings of Humanities Panels will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Heather C. Gottry, Acting Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential and/or information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* July 10, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for African and Middle Eastern Studies (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

2. *Date:* July 11, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Asian Studies II (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

3. *Date:* July 11, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Asian Studies I (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

4. *Date:* July 12, 2007.
Time: 9 a.m. to 5:30 p.m.
Room: 421.
Program: This meeting will review applications for Art and Anthropology, submitted to the Office of Challenge Grants, at the May 1, 2007 deadline.

5. *Date:* July 12, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for American History and Studies II (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

6. *Date:* July 12, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for American History and Studies I (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

7. *Date:* July 16, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Digital Humanities Fellowships II (FX) in Digital Humanities Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

8. *Date:* July 17, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Humanities I (HR) in Faculty Research Awards, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

9. *Date:* July 17, 2007.
Time: 9 a.m. to 5:30 p.m.
Room: 421.
Program: This meeting will review applications for Academic & Research Institutions, submitted to the Office of Challenge Grants, at the May 1, 2007 deadline.

10. *Date:* July 18, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Digital Humanities Fellowships I (FX) in Digital Humanities Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

11. *Date:* July 19, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for British Literature I (FA) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

12. *Date:* July 19, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for British Literature II (FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

13. *Date:* July 19, 2007.
Time: 9 a.m. to 5:30 p.m.
Room: 421.
Program: This meeting will review applications for History Organizations,

submitted to the Office of Challenge Grants, at the May 1, 2007 deadline.

14. *Date:* July 23, 2007.
Time: 2 p.m. to 4 p.m.
Room: 421.
Program: This meeting, which will be by teleconference, will review applications for Digital Humanities, submitted to the Office of Challenge Grants, at the May 1, 2007 deadline.

15. *Date:* July 23, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Art History I (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

16. *Date:* July 23, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315
Program: This meeting will review applications for Anthropology and Archaeology (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

17. *Date:* July 24, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Latin American Studies I (FA) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

18. *Date:* July 24, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Latin American Studies II (FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

19. *Date:* July 30, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Art History II (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

20. *Date:* July 30, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for American Studies (FA/FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

21. *Date:* July 31, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for European History I (FA) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

22. *Date:* July 31, 2007.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for European History II (FB) in Fellowships, submitted to the Division of Research Programs, at the May 1, 2007 deadline.

Heather C. Gottry,

Acting Advisory Committee, Management Officer.

[FR Doc. E7–12250 Filed 6–22–07; 8:45 am]

BILLING CODE 7536–01–P

NEIGHBORHOOD REINVESTMENT CORPORATION

Neighborworks® America Twenty-Ninth Annual Board of Directors Meeting; Sunshine Act

TIME AND DATE: 2 p.m., Wednesday, June 27, 2007.

PLACE: 1325 G Street, NW., Suite 800, Boardroom, Washington, DC 20005.

STATUS: Open.

CONTACT PERSON FOR MORE INFORMATION: Erica Hall, Assistant Corporate Secretary, (202) 220–2376; *ehall@nw.org.*

AGENDA:

I. Call To Order.
II. Approval of the Minutes.
III. Summary Report of the Corporate Administration Committee.
IV. Summary Report of the Finance, Budget and Program Committee.
V. Financial Report.
VI. Emergency Executive Succession Plan.
VII. Draft Delegation of Authority to CEO.
VIII. Chief Executive Officer's Quarterly Management Report.
IX. Adjournment.

Erica Hall,

Assistant Corporate Secretary.

[FR Doc. 07–3105 Filed 6–20–07; 3:55 pm]

BILLING CODE 7570–02–M

NUCLEAR REGULATORY COMMISSION

Commonwealth of Pennsylvania: Draft NRC Staff Assessment of a Proposed Agreement Between the Nuclear Regulatory Commission and the Commonwealth of Pennsylvania

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of a proposed agreement with the Commonwealth of Pennsylvania.

SUMMARY: By letter dated November 9, 2006, Governor Edward G. Rendell of Pennsylvania requested that the U. S. Nuclear Regulatory Commission (NRC or Commission) enter into an Agreement with the Commonwealth as authorized by Section 274 of the Atomic Energy Act of 1954, as amended (Act).

Under the proposed Agreement, the Commission would give up, and Pennsylvania would take over, portions of the Commission's regulatory authority exercised within the Commonwealth. As required by the Act, the NRC is publishing the proposed Agreement for public comment. The NRC is also publishing the summary of an assessment by the NRC staff of the Pennsylvania regulatory program. Comments are requested on the proposed Agreement, especially its effect on public health and safety. Comments are also requested on the draft NRC staff assessment, the adequacy of the Pennsylvania program, and the Commonwealth's program staff, as discussed in this notice.

The proposed Agreement would release (exempt) persons who possess or use certain radioactive materials in Pennsylvania from portions of the Commission's regulatory authority.

The Act requires that the NRC publish those exemptions. Notice is hereby given that the pertinent exemptions have been previously published in the **Federal Register** and are codified in the Commission's regulations as 10 CFR Part 150.

DATES: The comment period expires July 18, 2007. Comments received after this date will be considered if it is practical to do so, but the Commission cannot assure consideration of comments received after the expiration date.

ADDRESSES: Written comments may be submitted to Mr. Michael T. Lesar, Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, Washington, DC 20555–0001. Comments may be submitted electronically at *nrcrep@nrc.gov.*

The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at (800) 397–4209, or (301) 415–4737, or by e-mail to *pdr@nrc.gov.*

Copies of comments received by NRC may be examined at the NRC Public Document Room, 11555 Rockville Pike,

Public File Area O–1–F21, Rockville, Maryland. Copies of the request for an Agreement by the Governor of Pennsylvania including all information and documentation submitted in support of the request, and copies of the full text of the NRC Draft Staff Assessment are also available for public inspection in the NRC's Public Document Room—ADAMS Accession Numbers: ML070240128, ML063400549, ML070240055, ML063330295, ML070290041, ML070290046, ML070260116, ML070260179, ML070260026, ML070260119, ML070250054, ML063400559, ML070790604, ML070790609, ML070790612, ML070790616, ML070790620, and ML070890378.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew N. Mauer, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone (301) 415–3962 or e-mail to *anm@nrc.gov.*

SUPPLEMENTARY INFORMATION: Since Section 274 of the Atomic Energy Act of 1954, as amended (Act) was added in 1959, the Commission has entered into Agreements with 34 States. The Agreement States currently regulate approximately 17,600 Agreement material licenses, while the NRC regulates approximately 4,400 licenses. Under the proposed Agreement, approximately 690 NRC licenses will transfer to Pennsylvania. The NRC periodically reviews the performance of the Agreement States to assure compliance with the provisions of Section 274.

Section 274e requires that the terms of the proposed Agreement be published in the **Federal Register** for public comment once each week for four consecutive weeks. This notice is being published in fulfillment of the requirement.

I. Background

(a) Section 274b of the Act provides the mechanism for a State to assume regulatory authority, from the NRC, over certain radioactive materials [1] and activities that involve use of the materials.

In a letter dated November 9, 2006, Governor Rendell certified that the Commonwealth of Pennsylvania has a program for the control of radiation hazards that is adequate to protect public health and safety within Pennsylvania for the materials and activities specified in the proposed Agreement, and that the Commonwealth desires to assume regulatory responsibility for these materials and activities. Included with the letter was the text of the proposed Agreement, which is shown in Appendix A to this notice.

The radioactive materials and activities (which together are usually referred to as the ''categories of materials'') that the Commonwealth of Pennsylvania requests authority over are:

(1) The possession and use of byproduct materials as defined in Section 11e.(1) of the Act;

(2) The possession and use of byproduct materials as defined in Section 11e.(3) of the Act;

(3) The possession and use of byproduct materials as defined in Section 11e.(4) of the Act;

(4) The possession and use of source materials;

(5) The possession and use of special nuclear materials in quantities not sufficient to form a critical mass; and

(6) The regulation of the land disposal of: byproduct materials as defined in Section 11e.(1), 11e.(3), or 11e.(4) of the Act; source; or special nuclear waste materials received from other persons.

(b) The proposed Agreement contains articles that:

- Specify the materials and activities over which authority is transferred;
- Specify the activities over which the Commission will retain regulatory authority;
- Continue the authority of the Commission to safeguard nuclear materials and restricted data;
- Commit the Commonwealth of Pennsylvania and NRC to exchange information as necessary to maintain coordinated and compatible programs;
- Provide for the reciprocal recognition of licenses;
- Provide for the suspension or termination of the Agreement; and
- Specify the effective date of the proposed Agreement.

The Commission reserves the option to modify the terms of the proposed Agreement in response to comments, to correct errors, and to make editorial changes. The final text of the Agreement, with the effective date, will be published after the Agreement is approved by the Commission, and signed by the NRC Chairman and the Governor of Pennsylvania.

(c) The regulatory program is authorized by law under the Radiation Protection Act (35 P.S. §§ 7110.101—7110.703). § Section 7110.201 provides the authority for the Governor to enter into an Agreement with the Commission. Pennsylvania law contains provisions for the orderly transfer of regulatory authority over affected licensees from the NRC to the Commonwealth. After the effective date of the Agreement, licenses issued by NRC would continue in effect as Pennsylvania licenses until the licenses expire or are replaced by State-issued licenses. NRC licenses transferred to Pennsylvania which contain requirements for decommissioning and express an intent to terminate the license when decommissioning has been completed under a Commission-approved decommissioning plan will continue as Pennsylvania licenses and will be terminated by Pennsylvania when the Commission-approved decommissioning plan has been completed.

Pennsylvania currently regulates the users of naturally-occurring and accelerator-produced radioactive materials. The Energy Policy Act of 2005 (EPAct) expanded the Commission's regulatory authority over byproduct materials as defined in Sections 11e.(3) and 11e.(4) of the Act, to include certain naturally-occurring and accelerator-produced radioactive materials. On August 31, 2005, the Commission issued a time-limited waiver (70 FR 51581) of the EPAct requirements. Under the proposed Agreement, Pennsylvania would assume regulatory authority for these radioactive materials. Therefore, if the proposed Agreement is approved, the Commission would terminate the time-limited waiver in Pennsylvania coincident with the effective date of the Agreement. Also, a notification of waiver termination would be provided in the **Federal Register** for the final Agreement.

(d) The NRC draft staff assessment finds that the Commonwealth of Pennsylvania Bureau of Radiation Protection of the Pennsylvania Department of Environmental Protection is adequate to protect public health and safety, and is compatible with the NRC program for the regulation of Agreement materials.

II. Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials

The NRC staff has examined the Pennsylvania request for an Agreement with respect to the ability of the radiation control program to regulate Agreement materials. The examination

[1] The radioactive materials, sometimes referred to as ''Agreement materials,'' are: (a) byproduct materials as defined in Section 11e.(1) of the Act; (b) byproduct materials as defined in Section 11e.(3) of the Act; (c) byproduct materials as defined in Section 11e.(4) of the Act; (d) source materials as defined in Section 11z. of the Act; and (e) special nuclear materials as defined in Section 11aa. of the Act, restricted to quantities not sufficient to form a critical mass.

was based on the Commission's policy statement ''Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement'' (46 FR 7540; January 23, 1981, as amended by policy statements published at 46 FR 36969; July 16, 1981 and at 48 FR 33376; July 21, 1983), and the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA–700, ''Processing an Agreement.''

(a) Organization and Personnel. The Agreement materials program will be located within the existing Bureau of Radiation Protection (BRP) of the Pennsylvania Department of Environmental Protection (PADEP). The Bureau will be responsible for all regulatory activities related to the proposed Agreement.

The educational requirements for the BRP staff members are specified in the Commonwealth of Pennsylvania personnel position descriptions, and meet the NRC criteria with respect to formal education or combined education and experience requirements. All current staff members hold at least bachelor's degrees in physical or life sciences, or have a combination of education and experience at least equivalent to a bachelor's degree. Several staff members hold advanced degrees, and all have had additional training plus working experience in radiation protection. Supervisory level staff each have at least seven years working experience in radiation protection.

The BRP performed and the NRC staff reviewed an analysis of the expected workload under the proposed Agreement. Based on the NRC staff review of the BRP's staff analysis, the BRP has an adequate number of staff to regulate radioactive materials under the terms of the Agreement. The BRP will employ a staff with at least the equivalent of 17.2 full-time professional/technical and administrative employees for the Agreement materials program.

Pennsylvania has indicated that the BRP has an adequate number of trained and qualified staff in place. Pennsylvania has developed qualification procedures for license reviewers and inspectors which are similar to the NRC's procedures. The technical staff are working with NRC license reviewers in the NRC Region I Office and accompanying NRC staff on inspections of NRC licensees in Pennsylvania. Pennsylvania is also actively further supplementing their experience through direct meetings, discussions, and facility walk-downs with NRC licensees in Pennsylvania, and through self-study, in-house training, and formal training.

In the course of the NRC staff's continued interactions with Pennsylvania, the NRC staff will confirm the assurances that Pennsylvania provided concerning having an adequate number of trained and qualified staff in place, based on Pennsylvania's staff needs analysis and qualification procedures. Specifically, the NRC staff will verify how BRP staff fit into the qualification process, which staff are qualified in certain areas, and the basis for the determinations.

(b) Legislation and Regulations. In conjunction with the rulemaking authority vested in the Environmental Quality Board by Section 302 of the Pennsylvania Radiation Protection Act 1984–147, PADEP has the requisite authority to promulgate regulations for protection against radiation. The law provides PADEP the authority to issue licenses, issue orders, conduct inspections, and to enforce compliance with regulations, license conditions, and orders. Licensees are required to provide access to inspectors.

The NRC staff verified that Pennsylvania adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 into Pennsylvania Code Title 25, Environmental Protection by reference. The NRC staff also verified that Pennsylvania adopted the relevant NRC regulations in 10 CFR 61 into Pennsylvania Code Title 25, Environmental Protection. The NRC staff also approved an order to implement Increased Controls requirements for risk-significant radioactive materials for certain Pennsylvania licensees under the proposed Agreement. As a result of the renumbering of 10 CFR 71 in 2004, Pennsylvania is proceeding with necessary revisions to their regulations to ensure compatibility, that will be effective by October 1, 2007. Therefore, on the proposed effective date of the Agreement, Pennsylvania will have adopted an adequate and compatible set of radiation protection regulations which apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. The NRC staff also verified that Pennsylvania will not attempt to enforce regulatory matters reserved to the Commission.

(c) Storage and Disposal. Pennsylvania has also adopted by reference the NRC requirements for the storage of radioactive material and for the land disposal of radioactive material as waste. The waste disposal requirements cover both the disposal of waste generated by the licensee and the disposal of waste generated by and received from other persons.

(d) Transportation of Radioactive Material. Pennsylvania has adopted the NRC regulations in 10 CFR 71 by reference. Part 71 contains the requirements licensees must follow when preparing packages containing radioactive material for transport. Part 71 also contains requirements related to the licensing of packaging for use in transporting radioactive materials. Pennsylvania will not attempt to enforce portions of the regulations related to activities, such as approving packaging designs, which are reserved to NRC.

(e) Recordkeeping and Incident Reporting. Pennsylvania has adopted by reference the Sections of the NRC regulations which specify requirements for licensees to keep records, and to report incidents or accidents involving materials.

(f) Evaluation of License Applications. Pennsylvania has adopted by reference the NRC regulations that specify the requirements a person must meet to get a license to possess or use radioactive materials. Pennsylvania has also developed a licensing procedures manual, along with the accompanying regulatory guides, which are adapted from similar NRC documents and contain guidance for the program staff when evaluating license applications.

(g) Inspections and Enforcement. Pennsylvania has adopted a schedule providing for the inspection of licensees as frequently as, or more frequently than, the inspection schedule used by the NRC. The program has adopted procedures for the conduct of inspections, reporting of inspection findings, and reporting inspection results to the licensees. Pennsylvania has also adopted procedures for the enforcement of regulatory requirements, and is authorized by law to enforce the State rules using a variety of sanctions, including the imposition and collection of civil penalties, and the issuance of orders to suspend, modify or revoke licenses, or to impound materials.

(h) Regulatory Administration. Pennsylvania is bound by requirements specified in Commonwealth law for rulemaking, issuing licenses, and taking enforcement actions. The program has also adopted administrative procedures to assure fair and impartial treatment of license applicants. Pennsylvania law prescribes standards of ethical conduct for Commonwealth employees.

(i) Cooperation with Other Agencies. Pennsylvania law deems the holder of an NRC license on the effective date of the proposed Agreement to possess a

like license issued by Pennsylvania. The law provides that these former NRC licenses will expire either 90 days after receipt from the radiation control program of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is later. In the case of NRC licenses that are terminated under restricted conditions required by 10 CFR 20.1403 prior to the effective date of the proposed Agreement, Pennsylvania deems the termination to be final despite any other provisions of Commonwealth law or rule. For NRC licenses that, on the effective date of the proposed Agreement, contain a license condition indicating intent to terminate the license upon completion of a Commission approved decommissioning plan, the transferred license will be terminated by Pennsylvania under the plan so long as the licensee conforms to the approved plan.

Pennsylvania also provides for ''timely renewal.'' This provision affords the continuance of licenses for which an application for renewal has been filed more than 30 days prior to the date of expiration of the license. NRC licenses transferred while in timely renewal are included under the continuation provision. The Pennsylvania Code provides exemptions from the Commonwealth's requirements for licensing of sources of radiation for NRC and U.S. Department of Energy contractors or subcontractors. The proposed Agreement commits Pennsylvania to use its best efforts to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against hazards of radiation, and to assure that Pennsylvania's program will continue to be compatible with the Commission's program for the regulation of Agreement materials. The proposed Agreement stipulates the desirability of reciprocal recognition of licenses, and commits the Commission and Pennsylvania to use their best efforts to accord such reciprocity.

III. Staff Conclusion

Section 274d of the Act provides that the Commission shall enter into an agreement under Section 274b with any State if:

(a) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the agreement materials within the State, and that the State desires to assume regulatory responsibility for the agreement materials; and

(b) The Commission finds that the State program is in accordance with the requirements of Section 274o, and in all other respects compatible with the Commission's program for the regulation of materials, and that the State program is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

The NRC staff has reviewed the proposed Agreement, the certification by the Commonwealth of Pennsylvania in the application for an Agreement submitted by Governor Rendell on November 9, 2006, and the supporting information provided by the staff of the Bureau of Radiation Protection of the Pennsylvania Department of Environmental Protection, and concludes that, except as discussed above in Section II. ''Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials,'' (a) ''Organization and Personnel,'' of this document, the Commonwealth of Pennsylvania satisfies the criteria in the Commission's policy statement *''Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement,''* and therefore, meets the requirements of Section 274 of the Act. The proposed Pennsylvania program to regulate Agreement materials, as comprised of statutes, regulations, and procedures, is compatible with the program of the Commission and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

With respect to discussion above in Section II. ''Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials,'' (a) ''Organization and Personnel,'' once the NRC staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, the staff will be able to conclude that area is satisfied.

Dated at Rockville, Maryland, this 18th day of June, 2007.

For the Nuclear Regulatory Commission.

Janet R. Schlueter,

Director, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs.

Appendix A

An Agreement Between the United States Nuclear Regulatory Commission and the Commonwealth of Pennsylvania for the Discontinuance of Certain Commission Regulatory Authority and Responsibility Within the Commonwealth Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended

Whereas, The United States Nuclear Regulatory Commission (the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011 *et seq.* (the Act), to enter into agreements with the Governor of any State/Commonwealth providing for discontinuance of the regulatory authority of the Commission within the Commonwealth under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1), (3), and (4) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

Whereas, The Governor of the Commonwealth of Pennsylvania is authorized under the Pennsylvania Radiation Protection Act, Act of July 10, 1984, P.L. 688, No. 147, as amended, 35 P.S. § 7110.101 *et seq.*, to enter into this Agreement with the Commission; and,

Whereas, The Governor of the Commonwealth of Pennsylvania certified on November 8, 2006, that the Commonwealth of Pennsylvania (the Commonwealth) has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the Commonwealth covered by this Agreement, and that the Commonwealth desires to assume regulatory responsibility for such materials; and,

Whereas, The Commission found on [date] that the program of the Commonwealth for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

Whereas, The Commonwealth and the Commission recognize the desirability and importance of cooperation between the Commission and the Commonwealth in the formulation of standards for protection against hazards of radiation and in assuring that Commonwealth and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

Whereas, The Commission and the Commonwealth recognize the desirability of the reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

Whereas, This Agreement is entered into pursuant to the provisions of the Act; Now, therefore, It is hereby agreed between the

Commission and the Governor of the Commonwealth acting on behalf of the Commonwealth as follows:

Article I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the Commonwealth under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

1. Byproduct materials as defined in Section 11e.(1) of the Act;
2. Byproduct materials as defined in Section 11e.(3) of the Act;
3. Byproduct materials as defined in Section 11e.(4) of the Act;
4. Source materials;
5. Special nuclear materials in quantities not sufficient to form a critical mass.
6. The regulation of the land disposal of all byproduct, source, and special nuclear waste materials covered by this Agreement;

Article II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to:

1. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
2. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
3. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear materials waste as defined in the regulations or orders of the Commission;
4. The regulation of the disposal of such other byproduct, source, or special nuclear materials waste as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be disposed without a license from the Commission;
5. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

Article III

With the exception of those activities identified in Article II.A.1 through 4, this Agreement may be amended, upon application by the Commonwealth and approval by the Commission, to include one or more of the additional activities specified in Article II, whereby the Commonwealth may then exert regulatory authority and responsibility with respect to those activities.

Article IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

Article V

This Agreement shall not affect the authority of the Commission under SubSection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

Article VI

The Commission will cooperate with the Commonwealth and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that Commission and Commonwealth programs for protection against hazards of radiation will be coordinated and compatible. The Commonwealth agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the Commonwealth and the Commission for protection against hazards of radiation and to assure that the Commonwealth's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The Commonwealth and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The Commonwealth and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

Article VII

The Commission and the Commonwealth agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other Agreement State. Accordingly, the Commission and the Commonwealth agree to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

Article VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the Commonwealth, or upon request of the Governor of the Commonwealth, may terminate or suspend all or part of this agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) Such termination or suspension is required to protect public health and safety, or (2) the Commonwealth has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274j of the Act, temporarily suspend all or part of this agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the Commonwealth has failed to take necessary steps. The Commission shall periodically review actions taken by the Commonwealth under this Agreement to ensure compliance with Section 274 of the Act which requires a Commonwealth program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

Article IX

This Agreement shall become effective on [date], and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [City, State] this [date] day of [month], [year].

For the United States Nuclear Regulatory Commission,

Dale E. Klein, Chairman.

For the Commonwealth of Pennsylvania,

Edward G. Rendell, Governor.

[FR Doc. 07–3072 Filed 6–22–07; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Compliance Assistance Resources and Points of Contact Available to Small Businesses

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice.

SUMMARY: In accordance with the Small Business Paperwork Relief Act of 2002 (44 U.S.C. 3520), the Office of Management and Budget (OMB) is publishing a ''list of the compliance assistance resources available to small

businesses'' and a list of the points of contacts in agencies ''to act as a liaison between the agency and small business concerns'' with respect to the collection of information and the control of paperwork. This information is posted on the following Web site: *http://www.business.gov/compliance_resources*.

FOR FURTHER INFORMATION CONTACT: David Rostker, Office of Information and Regulatory Affairs, Office of Management and Budget, e-mail: *drostker@omb.eop.gov*, telephone: (202) 395–3897. Inquiries may be submitted by facsimile to (202) 395–7285.

SUPPLEMENTARY INFORMATION: The Small Business Paperwork Relief Act of 2002 (Pub. L. 107–198) requires OMB to ''publish in the **Federal Register** and make available on the Internet (in consultation with the Small Business Administration) on an annual basis a list of the compliance assistance resources available to small businesses'' (44 U.S.C. 3504(c)(6)). OMB has, with the active assistance and support of the Small Business Administration (SBA) and the Business Gateway E-Government Initiative, assembled a list of the compliance assistance resources available to small businesses. This list is available today on the following Web site: *http://www.business.gov/compliance_resources*. There is also a link to this information on the OMB Web site.

In addition, under another provision of this Act, ''each agency shall, with respect to the collection of information and the control of paperwork, establish 1 point of contact in the agency to act as a liaison between the agency and small business concerns'' (44 U.S.C. 3506(i)(1)). The list of these contacts is available on the following Web site: *http://www.business.gov/compliance_contacts*.

Susan E. Dudley,

Administrator, Office of Information and Regulatory Affairs.

[FR Doc. E7–12215 Filed 6–22–07; 8:45 am]

BILLING CODE 3110–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for OMB Review; Comment Request for Extension of a Currently Approved Information Collection: Reemployment of Annuitants, 5 CFR 837.103

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, May 22, 1995), this notice announces that the Office of Personnel Management (OPM) has submitted to the Office of Management and Budget (OMB) a request for extension of a currently approved information collection. Section 837.103 of Title 5, Code of Federal Regulations, requires agencies to collect information from retirees who become employed in Government positions. Agencies need to collect timely information regarding the type and amount of annuity being received so the correct rate of pay can be determined. Agencies provide this information to OPM so a determination can be made whether the reemployed retiree's annuity must be terminated.

Approximately 3,000 reemployed retirees are asked this information annually. It takes each reemployed retiree approximately 5 minutes to provide the information for an annual estimated burden of 250 hours.

For copies of this proposal, contact Mary Beth Smith-Toomey on (202) 606–8358, Fax (202) 418–3251 or via E-mail to *MaryBeth.Smith-Toomey@opm.gov.* Please include a mailing address with your request.

DATES: Comments on this proposal should be received within 30 calendar days from the date of this publication.

ADDRESSES: Send or deliver comments to—

Pamela S. Israel, Chief, Operations Support Group, Center for Retirement and Insurance Services, U.S. Office of Personnel Management, 1900 E Street, NW., Room 3349, Washington, DC 20415–3540; and

Brenda Aguilar, OPM Desk Officer, Office of Information & Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW., Room 10235, Washington, DC 20503.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Cyrus S. Benson, Team Leader, Publications Team, RIS Support Services/Support Group, (202) 606–0623.

U.S. Office of Personnel Management.

Tricia Hollis,

Chief of Staff.

[FR Doc. E7–12232 Filed 6–22–07; 8:45 am]

BILLING CODE 6325–38–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension: Form N–1A, SEC File No. 270–21, OMB Control No. 3235–0307.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget (''OMB'') for extension and approval.

Form N–1A (17 CFR 239.15A and 274.11A) is the form used by open-end management investment companies (''funds'') [1] under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''Investment Company Act'') and/or to register their securities under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) (''Securities Act''). Section 5 of the Securities Act (15 U.S.C. 77e) requires the filing of a registration statement prior to the offer of securities to the public and that the statement be effective before any securities are sold, and Section 8 of the Investment Company Act (15 U.S.C. 80a–8) requires a fund to register as an investment company. Form N–1A also permits funds to provide investors with a prospectus and a statement of additional information (''SAI'') covering essential information about the fund when it makes an initial or additional offering of its securities. Section 5(b) of the Securities Act requires that investors be provided with a prospectus containing the information required in a registration statement prior to the sale or

[1] Management investment companies typically issue shares representing an undivided proportionate interest in a changing pool of securities, and include open-end and closed-end companies. See T. Lemke, G. Lins, A. Smith III, Regulation of Investment Companies, Vol. I, ch. 4, § 4.04, at 4–5 (2002). An open-end company is a management company that is offering for sale or has outstanding any redeemable securities of which it is the issuer. A closed-end company is any management company other than an open-end company. See Section 5 of the Investment Company Act (15 U.S.C. 80a–5). Open-end companies generally offer and sell new shares to the public on a continuous basis. Closed-end companies generally engage in traditional underwritten offerings of a fixed number of shares and, in most cases, do not offer their shares to the public on a continuous basis.

at the time of confirmation or delivery of the securities. The form also may be used by the Commission in its regulatory review, inspection, and policy-making roles.

The Commission estimates that there are 77 initial registration statements and 2,320 post-effective amendments to initial registration statements filed on Form N–1A annually and that the average number of portfolios referenced in each initial filing and post-effective amendment is 4.9. The Commission further estimates that the hour burden for preparing and filing a post-effective amendment on Form N–1A is 111 hours per portfolio. The total annual hour burden for preparing and filing post-effective amendments is 1,261,848 hours (2,320 post-effective amendments × 4.9 portfolios × 111 hours per portfolio). The estimated annual hour burden for preparing and filing initial registration statements is 313,336 hours (77 initial registration statements × 4.9 portfolios × 830.47 hours per portfolio). The total annual hour burden for Form N–1A, therefore, is estimated to be 1,575,184 hours (1,261,848 hours + 313,336 hours).

The information collection requirements imposed by Form N–1A are mandatory. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, Virginia 22312 or send an e-mail to: *PRA_Mailbox@sec.gov*.

Dated: June 18, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–12193 Filed 6–22–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of American Teletronics, Inc., n/k/a: Shine Holdings, Inc., Order of Suspension of Trading

June 21, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of American Teletronics, Inc., n/k/a Shine Holdings, Inc., because it has not filed any periodic reports since the period ended September 30, 1996.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in American Teletronics, Inc., n/k/a Shine Holdings, Inc., is suspended for the period from 9:30 a.m. EDT on June 21, 2007, through 11:59 p.m. EDT on July 5, 2007.

By the Commission.

Nancy M. Morris,

Secretary.

[FR Doc. 07–3113 Filed 6–11–07; 11:30 am]

BILLING CODE 8010–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #10866 and #10867]

Kansas Disaster Number KS–00018

AGENCY: Small Business Administration.

ACTION: Amendment 7.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Kansas (FEMA–1699–DR), dated 05/06/2007.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 05/04/2007 through 05/18/2007.

Effective Date: 06/15/2007.

Physical Loan Application Deadline Date: 07/05/2007.

EIDL Loan Application Deadline Date: 02/06/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of Kansas, dated 05/06/2007 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: Osage.

Contiguous Counties: Kansas, Franklin.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E7–12124 Filed 6–22–07; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 5845]

30-Day Notice of Proposed Information Collection: Forms DS–2053, DS–3024, DS–3025, and DS–3026; Medical Examination for Immigrant or Refugee Applicant; OMB Control Number 1405–0113

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* Medical Examination for Immigrant or Refugee Applicant.
- *OMB Control Number:* 1405–0113.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Office of Visa Services (CA/VO).
- *Form Number:* DS–2053, DS–3024, DS–3025, DS–3026.
- *Respondents:* Immigrant visa and refugee applicants.
- *Estimated Number of Respondents:* 630,000 per year.
- *Estimated Number of Responses:* 630,000 per year.
- *Average Hours per Response:* 1 hour.
- *Total Estimated Burden:* 630,000 hours annually.

• *Frequency:* Once per application.
• *Obligation to Respond:* Required to Obtain Benefit.

DATES: Submit comments to the Office of Management and Budget (OMB) for up to 30 days from June 25, 2007.

ADDRESSES: Direct comments and questions to Katherine Astrich, the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB), who may be reached at 202–395–4718. You may submit comments by any of the following methods:

• *E-mail: Katherine__T.__Astrich@omb.eop.gov*. You must include the DS form number, information collection title, and OMB control number in the subject line of your message.
• *Mail (paper, disk, or CD-ROM submissions):* Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503.
• *Fax:* 202–395–6974

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed information collection and supporting documents, to Andrea Lage of the Office of Visa Services, U.S. Department of State, 2401 E Street, NW., L–603, Washington, DC 20522, who may be reached at (202) 663–1221 or *lageab@state.gov.*

SUPPLEMENTARY INFORMATION: We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary to properly perform our functions.
• Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
• Enhance the quality, utility, and clarity of the information to be collected.
• Minimize the reporting burden on those who are to respond.

Abstract of proposed collection: INA Section 221(d) requires that prior to the issuance of an immigrant visa the applicant undergo a physical and mental examination. The results of the medical examination are used to determine the alien's eligibility for such a visa under INA 212(a)(1). INA Section 412(b)(4)(B) requires that the United States Government ''provide for the identification of refugees who have been determined to have medical conditions affecting the public health and requiring treatment.'' Form DS–2053, Medical Examination for Immigrant or Refugee Applicant; Form DS–3024, Chest X-Ray and Classification Worksheet; Form DS–3025, Vaccination Documentation Worksheet; and Form DS–3026, Medical History and Physical Examination Worksheet, are designed to record the results of the medical examination. The panel physician performs the medical examination of the applicant and completes the forms.

Methodology: The medical forms are sent to the applicant in the applicant's package. The applicant takes the forms to the panel physician to use during the medical examination. The panel physician completes the medical examination and fills out the forms. The forms are then submitted in hard copy to the consular officer for processing.

Dated: June 7, 2007.

Stephen A. Edson,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. E7–12252 Filed 6–22–07; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice: 5846]

30-Day Notice of Proposed Information Collection: Recording, Reporting, and Data Collection Requirements Under 22 CFR Part 62 (DS–7000), the Exchange Visitor Program Application (Form DS–3036) and Update of Information on Exchange Visitor Program Sponsor (Form DS–3037); OMB No. 1405–0147

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995.

• Title of Information Collection: Recording, Reporting, and Data Collection Requirements under 22 CFR Part 62 (DS–7000), the Exchange Visitor Program Application (Form DS–3036) and Update of Information on Exchange Visitor Program Sponsor (Form DS–3037).
• OMB Control Number: OMB No. 1405–0147.
• Type of Request: Revision of a Currently Approved Collection.
• Originating Office: Office of Exchange Coordination and Designation—ECA/EC/AG and ECA/EC/PS.
• Form Number: Forms DS–3036, DS–3037 and DS–7000.
• Respondents: U.S. government, and public and private organizations wishing to become designated sponsors and Department of State designated sponsors.
• Estimated Number of Respondents: 191, 810 (DS–3036—150; DS–3037—1460; DS–7000—190,200).
• Estimated Number of Responses: 1,623,445 (DS–3036—150 annually; DS–3037—2920 annually; DS–7000—1,620,375).
• Average Hours per Response: DS–3036—1 hour; DS–3037—20 minutes; DS–7000—45 minutes.
• Total Estimated Burden: 1,216,404 (DS–3036—150 hours; DS–3037—973 hours; DS–7000—1,215,281 hours).
• Frequency: On Occasion.
• Obligation to Respond: Required to Obtain or Retain a Benefit.

DATES: Submit comments to the Office of Management and Budget (OMB) for up to 30 days from June 25, 2007.

ADDRESSES: Direct comments and questions to Katherine Astrich, the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB), who may be reached at 202–395–4718. You may submit comments by any of the following methods:

• E-mail: *kastrich@omb.eop.gov.* You must include the DS form number, information collection title, and OMB control number in the subject line of your message.
• Mail (paper, disk, or CD–ROM submissions): Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503.
• Fax: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Director, Office of Exchange Coordination and Designation, U.S. Department of State, SA–44, 301 4th Street, SW., Room 734, Washington, DC 20547; or e-mail at *jexchanges@state.gov.*

SUPPLEMENTARY INFORMATION: We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary to properly perform our functions.
• Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
• Enhance the quality, utility, and clarity of the information to be collected.
• Minimize the reporting burden on those who are to respond.

Abstract of Proposed Collection

The collection is the continuation of information collected and needed by the Bureau of Educational and Cultural Affairs in administering the Exchange Visitor Program (J–Visa) under the provisions of the Mutual Educational and Cultural Exchange Act, as amended. The forms have been revised to include the addition of a new category of Intern.

Methodology

Access to Forms DS–3036 and DS–3037 are found in the Student and Exchange Visitor Information System (SEVIS), *http://www.ice.gov/sevis.*

Dated: June 1, 2007.

Stanley S. Colvin,

Director, Office of Exchange Coordination & Designation, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. E7–12272 Filed 6–22–07; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Second Meeting, Special Committee 215 Aeronautical Mobile Satellite (Route) Services Next Generation Satellite Services and Equipment

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of RTCA Special Committee 215, Aeronautical Mobile Satellite (Route) Services, Next Generation Satellite Services and Equipment.

SUMMARY: The FAA is issuing this notice to advise the public of a second meeting of RTCA Special Committee 215, Aeronautical Mobile Satellite (Route) Services, Next Generation Satellite Services and Equipment.

DATES: The Meeting will be held July 23–24, 2007 starting July 23, at 1 p.m.–5 p.m. or later as required and July 24 from 9 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1828 L Street, NW., Suite 805, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington DC 20036; telephone (202) 833–9339; fax (202) 833–9434; Web site *http://www.rtca.org* for directions. **Note:** Dress is business casual.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for a Special Committee 215 meeting. The agenda will include:

- July 23–24:
- Opening Plenary Session (Welcome, Introductions, and Administrative Remarks, Review and Approval of Agenda for Second Plenary).
- Review and Approval of First Meeting Summary (215–008; RTCA Paper No. 141–07/SC215–003).
- Outcome of PMC Meeting—Request for Change to SC–215 TOR.

FAA Issue Table—Outstanding Actions (215–005).

- NSF-Radio Astronomy Issue (Iridium).
- Iridium-Inmarsat Interference White Paper (Aircell).
- Use of Proprietary Information.
- DO–262—Reports from Drafting Groups; Review of Document Outlines.
- Section 1—Overview (M. Meza, Iridium).
- Section 2—Avionics Subsystem Definition/Overall Requirements (J. Becker, Wingspeed).
- Section 3—Antenna (K. Blomgren, Dayton-Granger).
- Section 4—Transceiver (M. Meza, Iridium).
- Section 5—Avionics Design and Performance (A. Jabs, ICG).
- Section 6—Avionics Equipment Performance Verification (B. Pemberton, ARINC).
- Section 7—Aircraft Installation Design Requirements (S. Niessner, Aircell).
- Section 8—Requirements Mapping (M. Meza, Iridium).
- DO–270.
- Report from FAA-Iridium Meetings.
- Iridium Review of DO–270 Requirements.
- Discussion of Requirements for Normative Appendix.
- Closing Plenary Session (Other Business, Schedule Next Plenary Meeting, Adjourn).

Attendance is open to the interested public but limited to space availability. With the approval of the chairmen, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on June 14, 2007.

Francisco Estrada C.,

RTCA Advisory Committee.

[FR Doc. 07–3069 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program; Portland International Airport

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by the Portland International Airport under the provisions of 49 U.S.C. (the Aviation Safety and Noise Abatement Act, hereinafter referred to as ''the Act'') and 14 CFR part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On December 13, 2006, the FAA determined that the noise exposure maps submitted by the Portland International Airport under Part 150 were in compliance with applicable requirements. On June 7, 2007, the FAA approved the Portland International Airport noise compatibility program. Most of the recommendations of the program were approved.

DATES: *Effective Dates:* The effective date of the FAA's approval of the Portland International Airport noise compatibility program is June 7, 2007.

FOR FURTHER INFORMATION CONTACT: Cayla Morgan, Federal Aviation Administration, Seattle Airports District Office, 1601 Lind Ave., SW., Renton, WA 98057–3356, (425) 227–2653. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise compatibility program for Portland International Airport, effective June 7, 2007.

Under section 47504 of the Act, an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the noise exposure maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with

14 Code of Federal Regulations (14 CFR) Part 150 is a local program, not a Federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measures should be recommended for action. The FAA's approval or disapproval of 14 CFR Part 150 program recommendations is measured according to the standards expressed in Part 150 and the Act and is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of 14 CFR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing non-compatible land uses around the airport and preventing the introduction of additional non-compatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in 14 CFR part 150, § 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, State, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Seattle Airports District Office in Seattle, Washington. Portland International Airport submitted to the FAA on December 6, 2006, the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from 2001 through 2006. The Portland International Airport noise exposure maps were determined 2001 through 2006. The Portland International Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on December 13, 2006. Notice of this determination was published in the **Federal Register** on December 20, 2006 (FR Volume 71, Number 244, pages 76420–76421).

The Portland International Airport study contains a proposed noise compatibility program comprised of actions designed for phased implementation by airport management and adjacent jurisdictions. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in section 47504 of the Act. The Faa began its review of the program on December 13, 2006, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new or modified flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained ten noise abatement measures, nine noise mitigation/land use compatibility measures, and eight administrative recommendations. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR part 150 have been satisfied. The overall program, therefore, was approved by the FAA effective June 7, 2007.

Outright approval was granted for 24 specific program elements. Pursuant to 49 U.S.C. 47504(b), no action was required for Noise Abatement Recommendation 8—Reduced Use of Reverse Thrust on Landing. Noise Mitigation Recommendation 10—Floating Home Sound Proofing was disapproved. The measure was disapproved because FAA is not aware of any published studies on the feasibility of sound attenuating floating homes, and Part 150 is not intended as a means to undertake new research. Administrative Measure 20—Propeller Retrofits was also disapproved because this measure called for the exploration of quiet technology and Part 150 is not intended as a means to undertake new research. Noise Mitigation Measure 12—Investigate Possible Solutions to Reduce Noise Exposure for Residents of Mobile Homes was removed from further consideration by the Port of Portland. Noise Mitigation Measure 18—Noise Disclosures for Prospective Purchasers at or above the 55 DNL Noise Contour was also removed from further consideration by the Port of Portland.

These determinations are set forth, in detail, in a Record of Approval signed by the Airports Division Manager, Northwest Mountain Region on June 7, 2007. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, including response to public comments, are available for review at the FAA office listed above and at the administrative offices of the Portland International Airport. The Record of Approval also will be available on-line at *http://www.faa.gov/arp/enviromental/14cfr150/index14.cfm.*

Issued in Renton, Washington on June 11, 2007.

Donna P. Taylor,

Manager, Airports Division, Northwest Mountain Region.

[FR Doc. 07–3070 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at the Pueblo Memorial Airport, Pueblo, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property

SUMMARY: The FAA proposes to rule and invite public comment on the release of land at the Pueblo Memorial Airport under the provisions of Section 125 of the Wendell H. Ford Aviation Investment Reform Act for the 21st Century (AIR 21)

DATES: Comments must be received on or before July 25, 2007.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Mr. Craig A. Sparks, Manager, Federal Aviation Administration, Northwest Mountain Region, Airports Division, Denver Airports District Office, 26805 E. 68th Ave., Suite 224, Denver, Colorado 80249.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Jerry Brienza, Airport Manager of Operations and Maintenance, Pueblo Memorial Airport, 31201 Bryan Circle, Pueblo, Colorado 81001.

FOR FURTHER INFORMATION CONTACT: Mr. Chris Schaffer, Project Manager, Federal Aviation Administration, Northwest Mountain Region, Airports Division,

Denver Airports District Office, 26805 E. 68th Ave., Suite 224, Denver, Colorado 80249.

The request to release property may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release property at the Pueblo Memorial Airport under the provisions of the AIR 21.

On May 30, 2007, the FAA determined that the request to release property at the Pueblo Memorial Airport submitted by the City of Pueblo, Colorado met the procedural requirements of the Federal Aviation Regulations, Part 155. The FAA may approve the request, in whole or in part, no later than July 27, 2007.

The following is a brief overview of the request:

The Pueblo Memorial Airport requests the release of 18.69 acres of non-aeronautical airport property, otherwise known as lot 8 of the Pueblo Memorial Industrial Park Subdivision, to the City of Pueblo, Colorado. The purpose of this release is to allow the City to sell the subject land that no longer serves any aeronautical purpose at the airport. The sale of this parcel will provide funds for airport improvements.

Any person may inspect the request by appointment at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, inspect the application, notice and other documents germane to the application in person at the Pueblo Memorial Airport, 31201 Bryan Circle, Pueblo, Colorado 81001.

Issued in Denver, Colorado on June 25, 2007.

Craig A. Sparks,

Manager, Denver Airports District Office.

[FR Doc. 07–3071 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Surface Transportation Environment and Planning Cooperative Research Program (STEP)

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: Section 5207 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) established the Surface Transportation Environment and Planning Cooperative Research Program (STEP). The general objective of the STEP is to improve understanding of the complex relationship between surface transportation, planning and the environment. SAFETEA–LU provides $16.875 million per year for fiscal years (FY) 2006–2009 to implement this new cooperative research program. STEP is the primary source of funds to conduct all Federal Highway Administration (FHWA) research on planning and environmental issues. In addition, Congress mandated several special studies and STEP will be the funding source for those projects. STEP will also address priorities identified in the U.S. Department of Transportation Research and Development Strategic Plan (section 508 of title 23 U.S.C.) including those related to highway safety benefits and congestion reduction.

The purpose of this notice is to announce revisions to the STEP implementation strategy for FY 2008 and to request suggested lines of research for the FY 2008 STEP via the STEP Web site at *http://www.fhwa.dot.gov/hep/step/index.htm.*

DATES: Suggestions for lines of research should be submitted to the STEP Web site on or before August 24, 2007.

FOR FURTHER INFORMATION CONTACT: Felicia Young, Office of Interstate and Border Planning, (202) 366–1263, *Felicia.young@fhwa.dot.gov;* or Grace Reidy, Office of the Chief Counsel, (202) 366–6226; Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this notice may be downloaded from the Office of the Federal Register's home page at *http://www.archives.gov* and the Government Printing Office's Web site at *http://www.access.gpo.gov.*

Background

Section 5207 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (Pub. L. 109–59, Aug. 10. 2005), established the Surface Transportation Environment and Planning Cooperative Research Program. STEP is a new cooperative research program for environment and planning research created in section 507 of Title 23, United States Code, Highways (23 U.S.C. 507). The general objective of the STEP is to improve understanding of the complex relationship between surface transportation, planning, and the environment.

Congestion reduction is an important element of the STEP. Transportation system congestion is one of the single largest threats to U.S. economic prosperity and the American way of life. In response to the challenges of congestion, in May 2006, the U.S. Department of Transportation (DOT) established the National Strategy to Reduce Congestion on America's Transportation Network (the ''Congestion Initiative''). The Congestion Initiative is a bold and comprehensive national program to reduce congestion on the Nation's roads, rails, runways and waterways.

Traffic congestion affects virtually every aspect of peoples' lives—where people live, where they work, where they shop and how much they pay for goods and services. According to 2003 figures, in certain metropolitan areas the average rush hour driver loses as many as 93 hours per year to travel delay—equivalent to more than 2 weeks of work, amounting annually to a virtual ''congestion tax'' as high as $1,598 per traveler in wasted time and fuel.[1] Nationwide, congestion imposes costs on the economy of over $65 billion per year,[2] a figure that has more than doubled since 1993, and that would be even higher if it accounted for the significant cost of unreliability to drivers and businesses, the environmental impacts of idle related auto emissions, or increase gasoline prices.

The STEP directly addresses congestion reduction efforts as part of the Planning Focus Area. Other STEP emphasis areas include goals and objectives that relate to congestion reduction. These include: Congestion; Air Quality and Global Climate Change, Bicycle/Pedestrian and Health, Environmental Streamlining/ Stewardship; U.S./Canada and U.S. Mexico Border Planning; Safety Planning; Freight Planning; Travel Modeling, etc. In addition, STEP outreach efforts continue to seek partnerships that can leverage limited research funding with other stakeholders and partners in order to increase the total amount of funding available to meet the Nation's surface transportation research needs including congestion reduction.

SAFETEA–LU provides $16.875 million per year for FY 2006–2009 to implement this new cooperative research program. Due to obligation

[1] Texas Transportation Institute (TTI__, 2005 Urban Mobility Report, May 2005 (*http://ttiltamu.edu/documents/mobility_report_2005.pdf*), Tables 1 and 2.

[2] TTI, 2005 Urban Mobility Report, p. 1.

limitations, rescissions, and congressional designation of Title V Research in SAFETEA–LU, it is anticipated that approximately $11.7 million of the $16.875 million authorized will be available each fiscal year.

On March 1, 2006, FHWA published a notice in the **Federal Register** (71 FR 10586) announcing the creation of an FHWA Web site to provide information regarding STEP and to solicit public input on the implementation strategy for this program. After reviewing the comments received in response to this notice, FHWA published a notice in the **Federal Register** on August 4, 2006 (71 FR 44348), announcing the posting of the final STEP Implementation Strategy on the STEP Web site. Additionally, this notice requested suggestions be submitted via the STEP Web site for the lines of research that should be undertaken in the STEP program.

The FHWA is issuing this notice: (1) To announce revisions to the STEP Implementation Strategy for the FY 2008 STEP, and (2) to solicit comments on proposed research activities to be undertaken in the FY 2008 STEP via the STEP Web site. The STEP Implementation Strategy was revised to: update information on the graph and chart regarding historical planning and environment research funding, and to add information about proposed FY 2008 STEP including proposed funding levels, goals and potential research activities.

Suggested lines of research activities for the FY 2008 STEP may include potential research ideas related to highway safety and the Congestion Initiative. Research activities related to the Congestion Initiative could specifically include ideas to relieve urban congestion; unleash private sector investment resources; promote operational and technological improvements and target major freight bottlenecks and expand freight policy outreach.

We invite the public to visit this Web site to obtain additional information on the STEP, as well as information on the process for forwarding comments to FHWA regarding the STEP implementation plan. The URL for the STEP Web site is *http://www.fhwa.dot.gov/hep/step/index.htm.* The FHWA will use this Web site as a major mechanism for informing the public regarding the status of the STEP.

Authority: Section 5207 of Public Law 109–59.

Issued on: June 8, 2007.

J. Richard Capka,

Federal Highway Administrator.

[FR Doc. E7–12127 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2007 28552]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intention to request extension of approval for three years of a currently approved information collection.

DATES: Comments should be submitted on or before August 24, 2007.

FOR FURTHER INFORMATION CONTACT: Joe Strassburg, Maritime Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: 202–366–4156; or e-mail: *joe.strassburg@dot.gov.* Copies of this collection also can be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: War Risk Insurance, Applications and Related Information.

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0011.

Form Numbers: MA–355; MA–528; MA–742; MA–828, and MA–942.

Expiration Date of Approval: Three years from date of approval by the Office of Management and Budget.

Summary of Collection of Information: As authorized by Section 1202, Title XII, Merchant Marine Act, 1936, as amended, the Secretary of the U.S. Department of Transportation may provide war risk insurance adequate for the needs of the waterborne commerce of the United States if such insurance cannot be obtained on reasonable terms from qualified insurance companies operating in the United States. This collection is required for the program. The collection consists of forms MA–355; MA–528; MA–742; MA–828, and MA–942.

Need and Use of the Information: The collected information is necessary to determine the eligibility of the applicant and the vessel(s) for participation in the war risk insurance program.

Description of Respondents: Vessel owners or charterers interested in participating in MARAD's war risk insurance program.

Annual Responses: 1,378.

Annual Burden: 576 hours.

Comments: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted to the Docket Clerk, U.S. DOT Dockets, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Comments also may be submitted by electronic means via the Internet at *http://dms.dot.gov/submit.* Specifically address whether this information collection is necessary for proper performance of the functions of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance the quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m. EDT (or EST), Monday through Friday, except Federal holidays. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov.*

Privacy Act:

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Authority: 49 CFR 1.66.

Dated: June 19, 2007.

By Order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–12244 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2007 28553]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this

notice announces the Maritime Administration's (MARAD's) intention to request extension of approval for three years of a currently approved information collection.

DATES: Comments should be submitted on or before August 24, 2007.

FOR FURTHER INFORMATION CONTACT: Frances Jerry, Maritime Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366–5861; or e-mail: *frances.jerry@dot.gov.* Copies of this collection also can be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Uniform Financial Reporting Requirements.

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0005.

Form Numbers: MA–172.

Expiration Date of Approval: Three years from date of approval by the Office of Management and Budget.

Summary of Collection of Information: The Uniform Financial Reporting Requirements are used as a basis for preparing and filing semi-annual and annual financial statements with the Maritime Administration. Regulations requiring financial reports to the Maritime Administration are authorized by Section 801 of the Merchant Marine Act, 1936 (46 U.S.C. 53101 note). Financial reports are also required by regulation of purchasers of ships from MARAD on credit, companies chartering ships from MARAD, and of companies having Title XI guarantee obligations (46 CFR Part 298).

Need and Use of the Information: The collected information is necessary for MARAD to determine compliance with regulatory and contractual requirements.

Description of Respondents: Vessel owners acquiring ships from MARAD on credit, companies chartering ships from MARAD, and companies having Title XI guarantee obligations.

Annual Responses: 67 responses.

Annual Burden: 1273 hours.

Comments: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted to the Docket Clerk, U.S. DOT Dockets, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Comments also may be submitted by electronic means via the Internet at *http://dms.dot.gov/submit.* Specifically address whether this information collection is necessary for proper performance of the functions of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance the quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m. EDT (or EST), Monday through Friday, except Federal holidays. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov.*

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Authority: 49 CFR 1.66.

Dated: June 19, 2007.

By Order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–12249 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2007 28551]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel HOLY GRAIL.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2007–28551 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before July 25, 2007.

ADDRESSES: Comments should refer to docket number MARAD–2007–28551. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel HOLY GRAIL is:

Intended Use: ''Carrying passengers for hire—six (6) or less.''

Geographic Region: ''Coastal waters of Hawaii.''

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov*.

Dated: June 19, 2007.

By order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–12248 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[USCG–2007–28532]

Port Dolphin Energy LLC, Port Dolphin Liquefied Natural Gas Deepwater Port License Application

AGENCY: Maritime Administration, DOT.

ACTION: Notice of application.

SUMMARY: The Coast Guard and the Maritime Administration announce that they have received an application for the licensing of a natural gas deepwater port and that the application contains the required information. This notice summarizes the applicant's plans and the procedures that will be followed in considering the application.

DATES: The Deepwater Port Act of 1974, as amended, requires a public hearing on this application within 240 days of the publication of this notice, and a decision on the application not later than 90 days after the final public hearing.

ADDRESSES: The public docket for USCG–2007–28532 is maintained by the: Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Docket contents are available for public inspection and copying, at this address, in room W12–140, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Facility's telephone is 202–366–9329, its fax is 202–493–2251, and its Web site for electronic submissions or for electronic access to docket contents is *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Ray Martin, U.S. Coast Guard, telephone: 202–372–1449, e-mail: *raymond.w.martin@uscg.mil* or Lieutenant Commander Brian Moore, U.S. Coast Guard, telephone: 202–372–1442, e-mail: *Brian.E.Moore@uscg.mil* or Chris Hanan, U.S. Maritime Administration, telephone: 202–366–1900, e-mail: *Christopher.Hanan@dot.gov*. If you have questions on viewing the Docket, call Renee V. Wright, Program Manager, Docket Operations, telephone: 202–493–0402.

SUPPLEMENTARY INFORMATION:

Receipt of application

On March 29, 2007, the Coast Guard and the Maritime Administration received an application from Port Dolphin Energy LLC for all Federal authorizations required for a license to own, construct, and operate a deepwater port authorized under the Deepwater Port Act of 1974, as amended, 33 U.S.C. 1501 *et seq.* (the Act). On June 15, 2007, we determined that the application contains all information required by the Act to initiate processing.

Background

According to the Act, a deepwater port is a fixed or floating man-made structure other than a vessel, or a group of structures, located beyond State seaward boundaries and used or intended for use as a port or terminal for the transportation, storage, and further handling of oil or natural gas for transportation to any State.

A deepwater port must be licensed by the Maritime Administrator (by delegated authority of the Secretary of Transportation, published on June 18, 2003 (68 FR 36496)). Statutory and regulatory requirements for licensing appear in 33 U.S.C. 1501 *et seq.* and in 33 CFR Part 148. Under delegations from and agreements between the Secretary of Transportation and the Secretary of Homeland Security, applications are processed by the Coast Guard and the Maritime Administration. Each application is considered on its merits.

The Act requires adherence to a strict timeline for processing an application. Once we determine that an application contains the required information, we must hold public hearings on the application within 240 days, and the Maritime Administrator must render a decision on the application within 330 days. We will publish additional **Federal Register** notices to inform you of these public hearings and other procedural milestones, including the environmental review. The Maritime Administrator's decision, and other key documents, will be filed in the public docket.

At least one public hearing must take place in each adjacent coastal state. For purposes of the Act, Florida is the adjacent coastal state for this application. Other states can apply for adjacent coastal state status in accordance with 33 U.S.C. 1508(a)(2).

Summary of the Application

Port Dolphin Energy LLC, proposes to own, construct, and operate a deepwater port, named Port Dolphin, in the Federal waters of the Outer Continental Shelf in the St. Petersburg (PB) blocks: PB545, PB589 and PB590, approximately 28 miles off the west coast of Florida to the southwest of Tampa Bay, in a water depth of approximately 100 feet. Port Dolphin would consist of a permanently moored unloading buoy system with two submersible buoys separated by a distance of approximately three miles. Each unloading buoy would be permanently secured to eight mooring lines, consisting of wire rope, chain, and buoyancy elements, each attached to anchor points on the seabed. Anchor points would consist most likely of driven piles.

The buoys would be designed to moor a specialized type of LNG vessel called a Shuttle and Regasification Vessel (SRV) of between 145,000 and 217,000 cubic meter capacity. SRV vessels are equipped to vaporize cryogenic LNG cargo to natural gas through an onboard closed loop vaporization system, and to odorize and meter gas for send-out by means of the unloading buoy to conventional subsea pipelines. The SRVs would moor to the unloading buoys which connect through the hull of the vessels to specially designed turrets that would enable the vessels to weathervane or rotate in response to prevailing wind, wave, and current directions. When the vessels are not present, the buoys would be submerged on a special landing pad on the seabed, 60–70 feet below the sea surface.

Each unloading buoy would connect through a 16-inch flexible riser and a 36-inch flowline to a Y intersection and then a 36-inch pipeline approximately 42 miles in length that would connect onshore in Port Manatee, Manatee County, Florida. The pipeline would connect with the Gulfstream Natural Gas System, LLC and Tampa Electric Company (TECO).

The 36-inch gas transmission line will make landfall on Port Manatee property. From there, the transmission pipeline would proceed in a generally easterly direction to the first interconnection point with the Gulfstream system at 3.6-miles. The Gulfstream Interconnection Station would occupy an approximately two-acre site. Up to approximately 80 percent of the natural gas or 800 million standard cubic feet per day (mmscfd) is expected to be delivered to the Gulfstream Pipeline.

The remaining portion of the natural gas, up to approximately 360 mmscfd, would be transported by 14-inch line to the TECO interconnection station, located 5.8-miles east of the Gulfstream interconnect. Only shuttle and regasification vessels (SRVs) would call on Port Dolphin. Offloading should

require between 4–8 days and when empty the SRV would disconnect from the buoy and leave the port.

Initially it is expected that Port Dolphin would be capable of a natural gas throughput of 400 mmscfd and would eventually be capable of 800 mmscfd with a peak capacity of 1200 mmscfd by having at least one SRV regasifying and discharging at all times. The system would be designed so that two SRVs can be moored simultaneously for continuous unloading of natural gas.

Port Dolphin Energy LLC is seeking Federal Energy Regulatory Commission (FERC) approval for the onshore pipelines concurrent with this deepwater port application. As required by FERC regulations, FERC will also maintain a docket for the FERC portion of the project. The docket numbers are CP07–191–000 and CP07–192–000. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call (866) 208–3767 or TYY, (202) 502–8659.

In addition, pipelines and structures such as the moorings may require permits under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act which are administered by the Army Corps of Engineers (USACE).

Port Dolphin will also require permits from the Environmental Protection Agency (EPA) pursuant to the provisions of the Clean Air Act, as amended, and the Clean Water Act, as amended.

The new pipeline will be included in the National Environmental Policy Act (NEPA) review as part of the deepwater port application process. FERC, EPA, and the USACE among others, are cooperating agencies and will assist in the NEPA process as described in 40 CFR 1501.6; will be participating in the scoping meetings; and will incorporate the EIS into their permitting processes. Comments sent to the FERC docket, EPA or USACE will also be incorporated into the DOT docket and EIS to ensure consistency with the NEPA Process.

Construction of the deepwater port would be expected to take approximately 22 months with startup of commercial operations following construction, should a license be issued. The deepwater port would be designed, constructed and operated in accordance with applicable codes and standards.

Privacy Act

The electronic form of all comments received into the DOT docket are available to any person and may be searched by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov*.

(Authority: 49 CFR 1.66)

Dated: June 20, 2007.

By Order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–12243 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2007–28067]

Highway Safety Programs; Model Specifications for Calibrating Units for Breath Alcohol Testers; Conforming Products List of Calibrating Units for Breath Alcohol Testers

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice.

SUMMARY: This notice amends the Model Specifications for Calibrating Units for Breath Alcohol Testers (Model Specifications) by adopting an alternate test procedure for evaluating the accuracy of both wet bath and dry gas breath alcohol calibrating units infra-red spectroscopy, as proposed in the **Federal Register** on August 13, 1997 (62 FR 43416). Published with this notice is an updated Conforming Products List of Calibrating Units for Breath Alcohol Testers (CPL) of calibrating units that meet the Model Specifications. This updated CPL includes 22 new listings—8 wet bath units and 14 dry gas units.

DATES: *Effective Date:* The amendments to the Model Specifications and the issuance of the CPL become effective on June 25, 2007.

FOR FURTHER INFORMATION CONTACT: *For technical issues:* Ms. J. De Carlo Ciccel, Office of Behavioral Safety Research, NTI–130, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone (202) 366–1694. *For legal issues:* Ms. Allison Rusnak, Office of Chief Counsel, NCC–113, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: On August 18, 1975 (40 FR 36167), NHTSA published a standard for Calibrating Units for Breath Alcohol Testers. A Qualified Products List of calibrating units for breath alcohol testers that met the standard was first issued on November 30, 1976 (41 FR 53389).

On December 14, 1984, NHTSA issued a notice to convert the mandatory standards for calibrating units for breath alcohol testers to Model Specification for such devices (49 FR 48865) and to establish a Conforming Products List (CPL) of calibrating units meeting the Model Specifications. Calibrating units provide known concentrations of ethanol vapor for the calibration or calibration checks of instruments that measure breath alcohol (BrAC).

On December 29, 1994, NHTSA published a notice amending the Model Specifications and updating the CPL for calibrating units (59 FR 67377). The notice also proposed and sought comments about providing an alternate test procedure using National Institute for Standards and Technology (NIST) Reference Gas Mixtures for evaluating the accuracy and precision of dry-gas ethanol calibrating units. The agency amended the Model Specifications on August 13, 1997 by incorporating the NIST test procedure (62 FR 43416). In that same notice, NHTSA updated the CPL and proposed an alternate test procedure for evaluating the accuracy and precision for evaluating wet bath and dry gas calibrating units using infra-red spectroscopy.

Having received no comments regarding the infra-red spectroscopy test procedure, this notice adopts the alternate procedure for evaluating wet bath and dry gas calibrating units using infra-red spectroscopy as proposed. This notice also amends the CPL of Calibrating Units for Breath Alcohol Testers, adding 8 wet bath units and 14 dry gas units.

A. Procedures for a Product Submission

Testing of calibrating units submitted by manufacturers to these Model Specifications will continue to be conducted by the DOT Volpe National Transportation Systems Center (VNTSC). Tests will continue to be conducted semi-annually or as necessary. Manufacturers wishing to submit calibrating units for testing must apply to NHTSA for a test date (Office of Behavioral Safety Research, NTI–130, 1200 New Jersey Avenue, SE., Washington, DC 20590, Telephone (202) 366–1694). Normally, at least 30 days will be required from the date of notification until the test can be scheduled. One week prior to the

scheduled initiation of the test program, the manufacturer shall deliver at least one unit of the device to be tested to: VNTSC, RTV–4F, 55 Broadway, Cambridge, MA 02142. The manufacturer shall be responsible for ensuring that the unit is operating properly. If the manufacturer wishes to submit a duplicate, backup unit, it may do so.

When a manufacturer delivers a device to be tested, it shall also deliver to VNTSC specifications and drawings that fully describe the unit and the Operator's Manual and Maintenance Manual normally supplied with purchase of the equipment. NHTSA will consider claims of confidentiality under 49 CFR Part 512.

The manufacturer shall also deliver the instructions that will accompany the device when it is sold. The instructions shall include information about the procedures to be followed to protect against possible condensation that might occur as a result of freezing during shipment and to correct for atmospheric pressure. The instructions shall also include information about any offsets that may apply to the use of a particular type of breath tester. NHTSA will examine these instructions to ensure that they provide sufficient information about these matters. Products submitted without this information will not be tested.

The manufacturer will have the right to check the calibrating unit between arrival at VNTSC and the start of the test and to ensure that the calibrating unit is in proper working condition. The manufacturer will have no access to the calibrating unit during the tests. Any malfunction of the calibrating unit that results in failure to complete any of the tests satisfactorily will result in a finding that it does not conform to the Model Specifications. If a unit fails to conform, it may be resubmitted for testing after appropriate corrective action has been taken.

On the basis of these results, NHTSA periodically will publish a CPL identifying the calibrating units that conform to the Model Specifications.

Re-testing of units will be conducted when necessary. NHTSA intends to modify and improve these Model Specifications as new data and improved test procedures become available. (The test procedures may be altered in specific instances, if necessary, to meet the unique design features of a calibrating unit). If these Model Specifications are modified, notification will be provided in the **Federal Register.** If NHTSA determines that re-testing to the modified specifications is necessary, a manufacturer whose equipment is listed on the CPL will be notified to resubmit the equipment for testing to the modified specifications only.

NHTSA reserves the right to test any unit on the CPL throughout its useful life to ensure that the unit is performing in accordance with the Model Specifications. If at any time a manufacturer plans to change the design of a calibrating unit currently on the CPL, the manufacturer shall submit the proposed changes to the NHTSA Office of Behavioral Safety Research for review. Based on this review, NHTSA will decide whether the change will require re-testing of the unit. Normally, such re-testing will be accomplished the next time testing is performed. Guidance to manufacturers on considerations governing this decision is available from NHTSA upon request.

NHTSA's Office of Behavioral Safety Research will be the point of contact for information about acceptance testing and field performance of equipment already on the list. NHTSA requests that users of calibrating units provide both acceptance and field performance data to NHTSA when such data is available. Information from users will be used to: (1) Help NHTSA determine whether units continue to perform according to the Model Specifications, and (2) ensure that field use does not indicate excessive breakdown or maintenance problems.

If information gathered indicates that a device on the CPL is not performing in accordance with the Model Specifications or demonstrates problems involving the device, NHTSA will direct VNTSC to conduct a special investigation. This investigation may include visits to users and additional tests of the unit obtained from the open market. If the investigation indicates that the units actually sold on the market are not meeting the Model Specifications, then the manufacturer will be notified that the unit may be removed from the CPL. The manufacturer shall have 30 days from the date of notification to reply.

Based on the VNTSC investigation and any data provided by the manufacturer, NHTSA will decide whether the unit should remain on the CPL. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems that led to the removal of the unit in question from the CPL.

B. Infra-Red Spectroscopy

This notice incorporates into the Model Specifications an alternate procedure for evaluating wet bath and dry gas calibrating units using infra-red spectroscopy. When infra-red spectroscopy is used, the wet bath or dry gas sample to be analyzed is passed into a chamber through which infra-red radiation is transmitted. The wavelength of the transmitted radiation is chosen so that some of it is absorbed by alcohol. According to the Beer-Lambert Law of absorption of radiation,[1] the amount of energy absorbed by the sample in the chamber is proportional to the concentration of the alcohol in the sample. By measuring the amount of radiation transmitted when the sample chamber is empty and the amount transmitted when the sample is present, the concentration of the alcohol in the sample can be determined.

The agency believes that use of infra-red spectroscopy offers important advantages. First, the technique can be used to evaluate both wet bath calibrating units and dry gas calibrating units because surface interactions do not affect the analysis. Second, standards used in the evaluations can be prepared at VNTSC, eliminating the necessity of obtaining standards from an outside source.

C. Conforming Products List

The CPL, which appears as an Appendix to this notice, lists the calibrating units that have been re-tested to date at the lower BACs (*i.e.,* at 0.020, 0.040, 0.080, and 0.160) and found to conform to the Model Specifications reprinted herein. The CPL also lists devices that have not been tested at the lower BAC levels (.020, .040, .080 and .0160), but were listed on the CPL for calibrating units on the basis that they were tested and found to conform to the earlier Model Specifications (49 FR 48864) when tested at BAC levels 0.050, 0.100 and 0.150. These devices are identified on the CPL with an asterisk.

The CPL published today includes 22 new listings—8 wet bath units and 14 dry gas units. The wet bath units include: CALWAVE dt–100, submitted by Davtech Analytical Service, Canada; Model 10–4D, Model 10–4D Revision A, Model 2100 (aka: Model 210021), Model 2100 Revision A, and 590 submitted by Guth Laboratories, Inc., Harrisburg, Pennsylvania; Alcotest CU 34 submitted by National Draeger, Inc., Durango, Colorado; and Model 3402C–2K submitted by RepCo Marketing, Inc., Raleigh, North Carolina. The dry gas units[2] include: 103 ppm/108L and 270

[1] Farrington Daniels & Robert Alberty, ''Physical Chemistry'' 3d. Ed. John Wiley & Sons, New York, 1996.

[2] The naming convention of the dry gas units added to the CPL today is illustrative of the ethanol

Continued

ppm/30L submitted by Airgas, Inc., (previously know as Gateway Airgas, Inc., A.G. Specialty Gas Co., or Acetylene Gas Co) St. Louis, Missouri; 115 ppm/34L, 115 ppm/103L, 230 ppm/34L, 230 ppm/103L, 260.5 ppm/58L, 260.5 ppm/537L, and 260.5 ppm/15L submitted by Air Liquide, CALGAZ, Cambridge, Maryland; and Scotty 28 0.040 BAC/28L, 0.045 BAC/28L, 0.080 BAC/28L, 0.100 BAC/28L, 0.105 BAC/28L submitted by Scott Specialty Gases, Inc., Plumsteadville, Pennsylvania. One device, Toxitest Model ABS120 by Federal Signal Corporation, is being removed from the CPL as it is no longer manufactured.

In consideration of the foregoing, NHTSA amends the Model Specifications for Calibrating United as set forth below.

Model Specifications for Calibrating United for Breath Alcohol Testers

1.0 Purpose and Scope

These specifications establish performance criteria and methods for testing of calibrating units which provide known concentrations of ethanol vapor for the calibration or calibration checks of breath alcohol testers. The results of this testing are intended for use in the conformance testing for the maintenance of a Conforming Products List for calibrating units.

2.0 Definitions

2.1 Conformance testing. Testing to check the conformance of a product with these model specifications in advance of and independent of any specific procurement action.

2.2 Concentration units. Blood alcohol concentration: grams alcohol per 100 milliliters blood or grams alcohol per 210 liters of breath in accordance with the Uniform Vehicle Code, Section 11–903(a)(5).[3] BrAC is often used to indicate that the measurement is a breath measurement, i.e. grams alcohol per 210 liters of breath.

2.3 Relative Standard Deviation (RSD). The ratio of the standard deviation (SD) of a series of measurements to the mean of the series expressed as a percentage:

$RSD = (SD/Mean) \times 100$ percent

2.4 Standard Deviation (SD). A common indication of precision in the measurement of the concentration of a succession of N vapor samples.

$SD = \{Sum\ (X_i - X_m)^2/(N-1)\}^{1/2}$

Where:

X_i = a single measurement result;
X_m = the average of the measurements;
N = the number of measurements made in the test.

2.5 Systematic Error (SE). An indication of the accuracy of the measurement of the concentration of a succession of vapor samples.

$SE = X_m$ − test BrAC

2.6 Least Squares Fit Calibration Curve. A Line fitted to a number of measurement pairs, one the independent value (X) and the other the dependent value (Y), over a measurement range.

The fitted line is of the form: $Y = a + bX$, where intercept, $a = Y_m - b_m$, and slope, $b = (SumX_iY_i - NX_m) / (SumX_i^2 - nX_m^2)$

3.0 Tests and Requirements

If the BrAC of the CU is fixed, perform the tests at the fixed BrAC; otherwise, prepare the CU for testing at 0.08 BrAC except as otherwise required in Test 1 below. Each of the tests requires 10 measurements to three decimal places using the test procedure specified in 3.1, 3.2, or 3.3, respectively. The CU will be operated according to the manufacturer's instructions. Unless otherwise specified, the tests will be performed in the absence of drafts and at prevailing normal laboratory temperature, humidity, and barometric pressure. Performance requirements are:

− 0.002 BrAC ≤ SE ≤ +0.002 BrAC; RSD ≤ 2%

Test 1. Precision and Accuracy. Test at each specified BrAc.

Test 1.1: 0.020 BrAC
Test 1.2: 0.040 BrAC
Test 1.3: 0.080 BrAC
Test 1.4: 0.160 BrAC

Test 2. Ambient Temperature. Use a temperature chamber controllable to ± °C. Soak the CU at the specified temperature for 1 hour, being careful to prevent drafts on the device, then test at that temperature.

Test 2.1: 10 °C
Test 2.2: 30 °C

Test 3. Input Power. If the CU is powered by nominal voltages of 120 volts AC of 12 volts DC, condition the device for one half hour at the appropriate input voltage specified below, then test at that voltage. Monitor the input power with a voltmeter accurate to ± 2% full scale in the range used and re-adjust the voltage, if necessary. If the voltage is Ac, conduct test 3.1 and 3.2.

If the voltage is DC, conduct tests 3.3 and 3.4.

Test 3.1: 108 Volts/AC
Test 3.2: 123 Volts/AC
Test 3.3: 11 Volts/DC
Test 3.4: 15 Volts/DC

Test 4. Electrical Safety Inspection. Examine the CU for protection of the operator from electrical shock. Examine for proper use of input power fuses, and verify that there are no exposed male connectors at high potential. Determine that overheating does not occur during operation and that undue fire hazards do not exist.

3.1 Test Procedure (Original, wet-bath calibrating units)

Equipment and Supplies: *Gas Chromatograph* capable of complete resolution of ethanol in test samples, with heated gas sampling valve. *Water bath* thermostated at 34 °C ± 0.1 °C. *Glass Reference Sample Bottles (300 ml capacity or greater) with Stopper and Inlet and Outlet Air Hoses* (see Figure 1). Hoses should be about 1/8'' OD Teflon tubing. *Reference Ethanol Solutions* prepared using Class A glassware and American Chemical Society reagent grade ethanol or USP grade ethanol. The purity of the ethanol used shall be compared with the National Institute of standards and Technology (NIST) Standard Reference Material for ethanol. Use the value of Harger, *et al.*, for the partition ratio for concentration of ethanol in headspace to concentration in solution at 34 °C, Ka/w = 0.000393 [4] to prepare two solutions which, when thermostated at 34 °C, produce headspace ethanol vapor concentrations that bracket the test BrAC by no more than ± 20%. Small Air Pump for bubbling air through reference solutions (see Figure 1).

Step 1. Prepare the Gas Chromatograph for measurement of vapor samples. Adjust instrument temperatures, gas flows, detector, and recording device for optimum response for ethanol. Prepare the CU for use according to manufacturer's instructions.

Step 2. Fill two reference solution bottles to ¾ full with above reference solutions. Insert stopper assemblies with bubble line and alcohol vapor line in place and put bottles in the water bath with water level up to the stopper. Connect air pump to bubble line. Connect alcohol vapor line to gas chromatograph sampling valve inlet fitting. Allow 1 hour for temperature equilibrium to be achieved.

concentration in the volume of nitrogen dry gas. Concentration is expressed in parts per million (ppm) or marketed as breath alcohol concentrations (BAC) and volume is expressed in Liters(L).

[3] Available from National Committee on Uniform Traffic Laws and Ordinances, 405 Church Street, Evanston, IL 60201.

[4] RN Harger, BB Raney, EG Bridwell, MF Kitchel J. Biol. Chem. 183, 197–213 (1950). Additional data from Harger in a private communication (see 49 FR 48869).

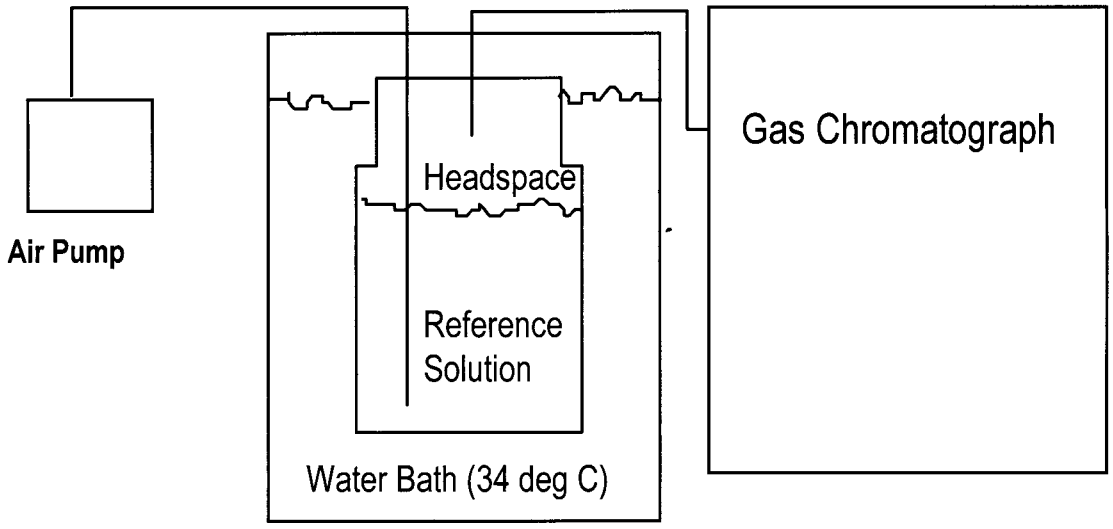
Step 3. Turn on air pump which has been pre-set to pump air through the reference solution bottle-gas chromatograph sampling assembly at a rate just sufficient to thoroughly flush the system in 10 seconds. After flushing is complete, allow the sample to relax to atmospheric pressure, then inject the reference sample onto the gas chromatograph column. In this way, obtain 5 chromatograms of one of the reference solution headspace ethanol vapors.

Step 4. Thoroughly flush the sample loop with vapors from the CU device, while avoiding over-pressurizing of the sampling system. To prevent condensation of alcohol, warm the transfer line if necessary. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 10 ethanol chromatograms using the CU device.

Step 5. Repeat step 3 using the second reference solution.

Step 6. Calculations. *Peak height to BrAC conversion factor.* For each ethanol peak obtained in Step 3 and Step 5, calculate a conversion factor for ethanol concentration by dividing the equivalent BrAC of the vapor sample by the peak height obtained for that sample. From the 10 samples, obtain the mean and the RSD of the conversion factors. If the RSD obtained fails to meet the criteria for RSD in 3.0, perform necessary troubleshooting and repeat the procedure from Step 1. Use the mean of the conversion factors to calculate the BrAC for each of the 10 ethanol peaks obtained in Step 4. Calculate the mean, the RSD, and the systematic error of the experimental BrACs.

Figure 1. Wet Bath Reference Sample Set-up. Sample lines 1/8" Teflon. The bubble line should extend at least 4 inches below surface of the solution. The length of the alcohol vapor line from the headspace to the gas chromatograph should be minimized.



3.2 Test Procedures (for dry gas calibrating units). Alternate Test Method using National Institute of Standards and Technology Reference Gas Mixtures (NISTRGMs) in place of wet bath reference samples

The following alternate method for the evaluation of dry gaseous ethanol calibration devices is presented.

Additional required material: For the alternate method for evaluation of dry gaseous ethanol calibration devices, the following will be required: Four cylinders of National Institute of Standards and Technology ethanol-in-inert gas Technical Reference Gas Mixtures (NISTRGMs) which span the BrAC range 0.01 to 0.16.

Alternate procedure for evaluation of dry gaseous ethanol calibration devices. This procedure substitutes the use of NISTRGMs in place of the wet bath reference samples when evaluating dry gas CUs.

Step A1. Connect one of the NISTRGM cylinders to the inlet of the gas chromatograph sampling valve and pass reference gas through the sampling system at a rate just sufficient to thoroughly flush the system in about 10 seconds. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 5 chromatograms of the reference gas.

Step A2. Repeat Step A1 for each of the four NISTRGM reference gas mixtures.

Step A3. Calculate the RSD of the concentration divided by peak height data obtained in Step A1 and Step A2. If the calculated RSD meets the criteria of 3.0, calculate the slope and intercept of the least squares fit calibration line for conversion of peak height to BrAC. Using the average peak height of each NISTRGM and the slope and intercept data, calculate the concentration of each NISTRGM. If the resulting concentrations are within the stated accuracy of the NISTRGM, proceed to Step A4.

Step A4. Connect the calibrating device to the inlet of the gas

chromatograph sampling system and allow the calibrating device gas to flow at a rate just sufficient to thoroughly flush the sampling system in about 10 seconds. Allow the sample to relax to atmospheric pressure, then inject the sample onto the column. In this way, obtain 10 chromatograms of the calibrating device gas.

Step A5. Calculations. Using the peak height data obtained in Step A4 and intercept and slope data obtained in Step A3, calculate the BrAC for each of the 10 peak heights. Calculate the mean, RSD, and systematic error of the calculated BrACs.

3.3 Test Procedures (for dry gas or wet bath calibrating units)

This alternate procedure uses infra-red spectroscopy that is suitable for evaluating ethanol vapor samples from either wet-bath CUs or from dry-gas CUs.

3.3.1 General. This method uses the Beer-Lambert Law of absorption of radiant energy by fluids.

$I = I_o \times e^{-abc}$

Where:

I_o is the energy entering the sample chamber of a spectrophotometer containing the sample to be analyzed.

I is the energy transmitted from the sample chamber.

a is the absorptivity of the sample.

b is the radiation path length of the sample chamber.

c is the concentration of the sample in the sample chamber.

A convenient form of the Beer-Lambert law is

$Ln(I_o/I) = abc$

where the term $Ln(I_o/I)$, the logarithm of the ratio of incident to transmitted energy, is called the absorbance of the sample. In the procedure described below, the terms a and b are treated as a single quantity, ab, and the term c is BrAC.

3.3.2 Test Procedure.

Equipment and Supplies. *Infra-red Spectrophotometer* with sample chamber that can be heated to above 40 °C. A non-dispersive instrument with appropriate band pass filters and configured to measure breath alcohol samples, such as an infra-red evidential breath tester listed on the NHTSA Conforming Products List for evidential breath testers may be used. The detector voltage of the instrument must be accessible for measurement. The sampling hoses of the device may be altered for more convenient processing of test samples. *Water bath* thermostated at 34 °C ± 0.1 °C. *Glass Reference Sample Bottles (300 ml capacity or greater) and Stoppers with Bubble and Alcohol Vapor lines* (see Figure 2). *Reference Ethanol Solutions* prepared using Class A glassware and American Chemical Society reagent grade ethanol or USP grade ethanol. The purity of the ethanol used shall be compared with the National Institute of Standards and Technology (NIST) Standard Reference Material for ethanol. Use the value of Harger, *et al.,* for the partition ratio for concentration of ethanol in headspace to concentration in solution at 34 °C, $K_{a/w} = 0.000393$[2] to prepare two aqueous alcohol solutions which bracket the test BrAC by no more than ± 20%. A cylinder of inert *Flushing Gas*, which is optically clear in the absorption region used for measurement. This gas will be used to flush the sample chamber of the spectrophotometer and to deliver reference headspace vapors and wet bath sample vapors into the sample chamber. *Pressure regulating valve with Teflon delivery hose* for controlling flow and delivery of flushing gas.

Step B1. Prepare the spectrometer for measurement of vapor samples. Prepare the CU for use according to manufacturer's instructions.

Step B2. Fill a reference sample bottles to ¾ full with water and two reference sample bottles to ¾ full with the above reference solutions. Insert stopper assemblies ensuring that the end of the bubble line reaches to at least 4 inches below the surface of the solution, then place the bottles in the water bath with water level up to the stopper. Allow 1 hour for temperature equilibrium to be achieved.

Step B3. Connect the bubble line of the sample bottle containing water only to the flushing gas valve and the vapor line to the spectrophotometer inlet and flush the sample chamber with water vapor and obtain the detector voltage reading. Then flush the detector chamber with flushing gas only and obtain the detector reading. Repeat 2 times to obtain 3 sets of readings. If the CU being evaluated is a wet bath device, skip this step and proceed to Step B4.

Step B4. In the manner of Step B3, obtain 5 sets of detector readings using one of the reference alcohol solution bottles.

Step B5. In the manner of Step B3, obtain 10 sets of detector readings from the CU being evaluated. If the CU is a wet bath device, use the flushing gas to fill the sample chamber, operating the device according to manufacturer's instructions. If the CU device is dry gas device, fill the sample chamber according to manufacturer's instructions.

Step B6. Repeat Step B5 using the other reference alcohol solution bottle.

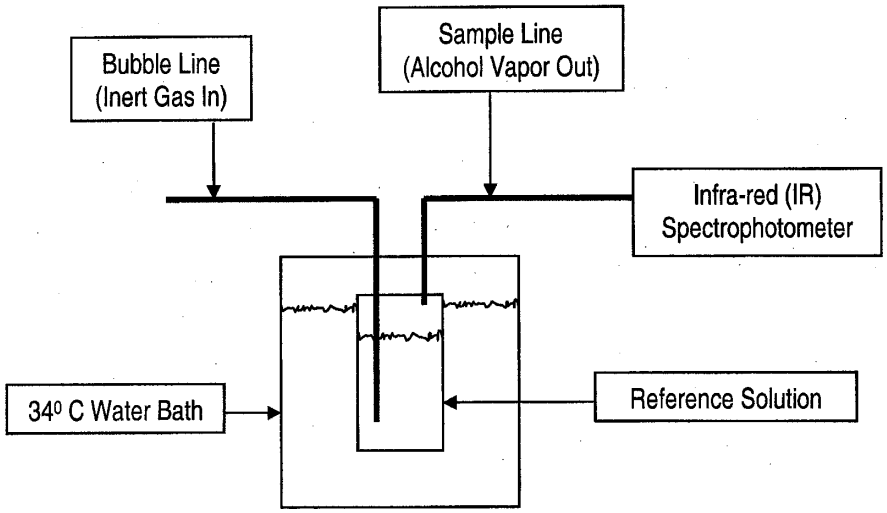
Step B7. Repeat Step B3.

Step B8. Calculations. For each measurement pair, I_o is the detector voltage obtained for the flushing gas alone in the sample chamber and I is the voltage obtained for the flushing gas with reference sample or test sample in the sample chamber corrected for water vapor absorption, i.e.; the detector voltage obtained for headspace reference samples at 0.000 BrAC. Use the average of the 6 voltage readings obtained for the water samples for the correction for water vapor absorption ($I = I_{sample} - I_{water}$). In the case of wet bath device samples, there is no correction for water vapor absorption. If the detector is biased, it will be the difference between the bias voltage and the above voltage.

Calculate the absorbance for each of the 10 reference samples. Divide each absorbance by the corresponding BrAC of the sample. Obtain the mean (which is the factor ab), SD, and RSD for the 10 ratios. If the RSD is more than 2%, troubleshoot the procedure and repeat.

Calculate the absorbance for each of the 10 CU test samples. Divide each by the ab factor to obtain the BrAC for each of the 10 CU samples. Obtain the mean, SD, RSD, and SE.

Figure 2. Equipment set-up. Bubble and sample lines 1/8" Teflon, minimized length. Depth of bubble line into reference solution at least 4". The alcohol vapor line from the headspace to the IR spectrophotometer should be minimized.



Appendix—Conforming Products List of Calibrating Units for Breath Alcohol Testers [Manufacturer and Calibrating Unit] [1]

CONFORMING PRODUCTS LIST OF CALIBRATING UNITS FOR BREATH ALCOHOL TESTERS

Manufacturers	Type of device	
	Dry gas	Wet bath
1. Airgas, Inc. (Formerly known as: Gateway Airgas, AG Specialty Gas, or Acetylene Gas Co.), St. Louis, MO		
• Ethanol Breath Alcohol Standard	X	
• 103 parts per million (ppm)/108 Liters (L)	X	
• 270 ppm/30L	X	.....
2. Air Liquide CALGAZ, Cambridge, MD		
• 115 ppm/34L	X	.....
• 115 ppm/105L	X	.....
• 230 ppm/34L	X	.....
• 230 ppm/105L	X	.....
• 260.5 ppm/58L	X	.....
• 260.5 ppm/537L	X	.....
• 260.5 ppm/15L	X	.....
3. CMI, Inc., Owensboro, KY		
• Toxitest II	.....	X
4. Davtech Analytical Services, Canada		
• CALWAVE dT–100	.....	X
5. Guth Laboratories, Inc., Harrisburg, PA		
• Model 34C Simulator (variations: Model 34C Cal DOJ, 34–C–FM, and 34C–NPAS)	.....	X
• Model 3412	.....	X
• Model 10–4 and 10–4D	.....	X
• Model 10–4D Revision A	.....	X
• Model 1214	.....	X
• Model 2100 (formerly Model 210021)	.....	X
• Model 2100 Revision A	.....	X
• 590	.....	X
6. Intoximeters, Inc., St. Louis, MO		
• Alco Breath Alcohol Standards*	X	.....
7. Lion Laboratories, Cardiff, Wales, UK (a subsidiary of CMI, Inc.)		
• AlcoCal Breath Alcohol Standard	X	
8. Liquid Technology Corp., Orlando, FL		
• Ethanol-in-Nitrogen	X	.....
9. Luckey Laboratories, Inc., San Bernardino, CA		
• Simulator*	.....	X

[1] Infra-red (IR) and fuel cell breath testers may be calibrated with either wet bath or dry gas CUs. However, it is inadvisable to use dry gas CUs when calibrating gas chromatograph EBTs.

CONFORMING PRODUCTS LIST OF CALIBRATING UNITS FOR BREATH ALCOHOL TESTERS—Continued

Manufacturers	Type of device	
	Dry gas	Wet bath
10. National Draeger, Inc., Durango, CO		
• Mark II–A	.....	X
• Alcotest CU 34	.....	X
11. PLD of Florida, Inc., Rockledge, FL		
• BA 500	.....	X
12. Protection Devices, Inc., U.S. Alcohol Testing, Inc., Rancho Cucamonga, CA		
• LS34 Model 6100*	.....	X
13. RepCo Marketing, Inc., Raleigh, NC		
• AS–1	.....	X
• Model 3402C	.....	X
• Model 3402C–2K	.....	X
14. Scott Specialty Gases, Inc., Plumsteadville, PA		
• Model EBS™ Gaseous Ethanol Breath Standard	X	.....
• Scotty 28 0.040 BAC/28L	X	.....
• Scotty 28 0.045 BAC/28L	X	.....
• Scotty 28 0.080 BAC/28L	X	.....
• Scotty 28 0.100 BAC/28L	X	.....
• Scotty 28 0.105 BAC/28L	X	.....
15. Smith & Wesson Electronic Co., Springfield, MA		
• Mark II–A Simulator*	.....	X
16. Systems Innovation, Inc., Hallstead, PA		
• True-Test MD 901*	.....	X
17. U.S. Alcohol Testing, Rancho Cucamonga, CA		
• Alco-Simulator 2000*	.....	X
• Alco-Simulator 61000	.....	X

*Six instruments marked with an asterisk (*) meet the Model Specifications in 49 FR 48864 (December 14, 1984), *i.e.* instruments tested at 0.050, 0.100, and 0.150). Instruments not marked with an asterisk meet the model specifications detailed in this notice, and were tested at 0.020, 0.040, 0.080, and 0.160 BrAC.

Authority: 23 U.S.C. 402; delegations of authority at 49 CFR 1.50 and 501.

Issued on: June 25, 2007.

Marilena Amoni,

Associate Administrator for the Office of Research and Program Development.

[FR Doc. 07–3060 Filed 6–22–07; 8:45 am]

BILLING CODE 4910–59–M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 290 (Sub–No. 5) (2007–3)]

Quarterly Rail Cost Adjustment Factor

AGENCY: Surface Transportation Board, Department of Transportation.

ACTION: Approval of rail cost adjustment factor.

SUMMARY: The Board has approved the third quarter 2007 rail cost adjustment factor (RCAF) and cost index filed by the Association of American Railroads. The third quarter 2007 RCAF (Unadjusted) is 1.197. The third quarter 2007 RCAF (Adjusted) is 0.558. The third quarter 2007 RCAF–5 is 0.531.

DATES: *Effective Date:* July 1, 2007.

FOR FURTHER INFORMATION CONTACT: Mac Frampton, (202) 245–0317. [Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision, which is available on our Web site *http://www.stb.dot.gov.* To purchase a copy of the full decision, write to, e-mail or call the Board's contractor, ASAP Document Solutions; 9332 Annapolis Rd., Suite 103, Lanham, MD 20706; e-mail *asapdc@verizon.net;* phone (202) 306–4004. [Assistance for the hearing impaired is available through FIRS: 1–800–877–8339.]

This action will not significantly affect either the quality of the human environment or energy conservation.

Pursuant to 5 U.S.C. 605(b), we conclude that our action will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Decided: June 19, 2007.

By the Board, Chairman Nottingham, Vice Chairman Buttrey, and Commissioner Mulvey.

Vernon A. Williams,

Secretary.

[FR Doc. E7–12163 Filed 6–22–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Submission for OMB Review; Comment Request—Interagency Guidance on Asset Securitization Activities

AGENCY: Office of Thrift Supervision (OTS), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. OTS is soliciting public comments on the proposal.

DATES: Submit written comments on or before July 25, 2007.

ADDRESSES: Send comments, referring to the collection by title of the proposal or by OMB approval number, to OMB and OTS at these addresses: Office of Information and Regulatory Affairs, Attention: Desk Officer for OTS, U.S. Office of Management and Budget, 725–17th Street, NW., Room 10235, Washington, DC 20503, or by fax to (202) 395–6974; and Information Collection Comments, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC

20552, by fax to (202) 906–6518, or by e-mail to *infocollection.comments@ots.treas.gov.* OTS will post comments and the related index on the OTS Internet Site at *http://www.ots.treas.gov.* In addition, interested persons may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov,* or send a facsimile transmission to (202) 906–7755.

FOR FURTHER INFORMATION CONTACT: For further information or to obtain a copy of the submission to OMB, please contact Marilyn K. Burton at *marilyn.burton@ots.treas.gov,* (202) 906–6467, or facsimile number (202) 906–6518, Litigation Division, Chief Counsel's Office, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: OTS may not conduct or sponsor an information collection, and respondents are not required to respond to an information collection, unless the information collection displays a currently valid OMB control number. As part of the approval process, we invite comments on the following information collection.

Title of Proposal: Interagency Guidance on Asset Securitization Activities.

OMB Number: 1550–0104.

Form Number: N/A.

Description: The collection applies to institutions engaged in asset securitization and consists of a written asset securitization policy, the documentation of fair value of retained interests, and a management information system to monitor securitization activities. Institutions use the collection as the basis for the safe and sound operation of their asset securitization activities. The agencies use the information to evaluate the quality of an institution's risk management practices.

Type of Review: Renewal.

Affected Public: Businesses or other for-profit; individuals.

Estimated Number of Respondents: 19.

Estimated Number of Responses: 19.

Estimated Frequency of Response: On occasion.

Estimated Total Burden: 190 hours.

Clearance Officer: Marilyn K. Burton, (202) 906–6467, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

OMB Reviewer: Desk Officer for OTS, Fax: (202) 395–6974, U.S. Office of Management and Budget, 725–17th Street, NW., Room 10235, Washington, DC 20503.

Dated: June 19, 2007.

Deborah Dakin,

Senior Deputy Chief Counsel Regulations and Legislation Division.

[FR Doc. E7–12280 Filed 6–22–07; 8:45 am]

BILLING CODE 6720–01–P

Federal Register

Monday,

June 25, 2007

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 111

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Final Rule

Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 1996N–0417] (formerly Docket No. 96N–0417)

RIN 0910–AB88

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule regarding current good manufacturing practice (CGMP) for dietary supplements. The final rule establishes the minimum CGMPs necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. The final rule is one of many actions related to dietary supplements that we are taking to promote and protect the public health.

DATES: This rule is effective August 24, 2007.

Compliance Dates: The compliance date is June 25, 2008; except that for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009; and except that for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010.

FOR FURTHER INFORMATION CONTACT: Vasilios H. Frankos, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1696.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Related Information

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) (Public Law 103–417) was signed into law. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 402(g) of the act (21 U.S.C. 342(g)). Section 402(g)(2) of the act provides, in part, that the Secretary of Health and Human Services (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g) of the act also stipulates that such regulations shall be modeled after CGMP regulations for food and may not impose standards for which there are no current and generally available analytical methodology. The final rule establishes, in part 111 (21 CFR part 111), the minimum CGMPs necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. The final rule is one of many actions related to dietary supplements that we are taking to promote and protect the public health.

In response to DSHEA, we issued an Advance Notice of Proposed Rulemaking (the 1997 ANPRM) in the **Federal Register** of February 6, 1997 (62 FR 5700). The 1997 ANPRM contained a CGMP outline submitted to us on November 20, 1995, by representatives of the dietary supplement industry. The 1997 ANPRM also asked nine questions that addressed issues that the industry outline did not. For example, we asked if there is a need to develop specific defect action levels (DALs) for dietary ingredients. We also asked whether a CGMP rule should require manufacturers to establish procedures to document, on a continuing or daily basis, that they followed pre-established procedures for making dietary supplements.

We received more than 100 comments in response to the 1997 ANPRM. We evaluated these comments before we drafted and ultimately issued a proposed rule on CGMPs for dietary ingredients and dietary supplements (which we discuss later in this section of this document).

Additionally, during 1999, we conducted a number of outreach activities related to dietary supplements. We held several public meetings to develop our overall strategy for achieving effective regulation of dietary supplements, which could include establishing CGMP regulations. We also held public meetings focused specifically on CGMPs and the economic impact that any CGMP rule for dietary ingredients and dietary supplements might have on small businesses. Further, we toured several dietary supplement manufacturing facilities to better understand the manufacturing processes and practices that potentially would be subject to CGMP requirements for dietary ingredients and dietary supplements (Refs. 1 through 6). These activities contributed to our knowledge about the industry.

In the **Federal Register** of March 13, 2003 (68 FR 12157), we published a proposed rule to establish CGMP requirements for dietary ingredients and dietary supplements (the 2003 CGMP Proposal). The preamble to the 2003 CGMP Proposal addressed the comments we had received regarding the nine questions in the 1997 ANPRM, discussed our legal authority to issue a CGMP rule, and described the basis for each proposed requirement.

The 2003 CGMP Proposal specifically requested comment on a variety of areas, including the need for written procedures and recordkeeping requirements. Although the proposed rule's comment period was scheduled to end on June 11, 2003, in the **Federal Register** of May 19, 2003 (68 FR 27008), we extended the comment period to August 11, 2003.

After we published the proposed rule, we conducted and/or participated in outreach activities related to dietary supplements and dietary ingredients. We held public stakeholder meetings on April 29, 2003, in College Park, MD, and on May 6, 2003, in Oakland, CA. We also held a public meeting, via satellite downlink, on May 9, 2003, with viewing sites at our district and regional offices throughout the country. These public meetings gave an overview of the proposed rule, and clarified specific points in the proposed rule. Since the public stakeholder meetings held as part of our outreach efforts, we also have participated in several meetings with industry and other interested parties which are reflected in the public docket.

We received approximately 400 comments in response to the proposal. The comments came from trade associations, government organizations and officials, manufacturers of dietary supplements and dietary ingredients, health care practitioners, consumer groups, and individuals. In general, the comments supported the idea of CGMPs, although many comments disagreed with specific aspects of the proposal.

Published elsewhere in this issue of the **Federal Register** we are also issuing an interim final rule that sets forth a procedure for requesting an exception to a CGMP requirement in this final rule. The interim final rule allows for submission to, and review by, FDA of an alternative to the required 100-percent identity testing of components that are dietary ingredients (as discussed in section X of this document (subpart E)), provided certain conditions are met. The interim final rule also includes a requirement for retention of records related to the FDA grant of an exception request.

II. How is the Final Rule Organized?

The 2003 CGMP Proposal was divided into eight subparts, with each subpart devoted to a particular topic. For example, proposed subpart A was titled ''General Provisions'' and contained sections describing the rule's scope, purpose, definitions, applicability of other statutory and regulatory provisions, and exclusions. As another example, proposed subpart B was titled ''Personnel'' and described microbial contamination and hygiene requirements, personnel qualification requirements, and supervisor requirements.

In response to comments seeking a simpler, more ''user-friendly'' final rule or seeking clarification of the rule's applicability to certain persons, items, or activities, and to reduce redundant provisions or combine similar provisions, we have reorganized the final rule into 16 subparts, with new subparts focusing on specific aspects of the manufacturing process or addressing specific issues. For example, the proposed rule placed all production and process control requirements for manufacturing, packaging, labeling, and laboratory operations in a single subpart (proposed subpart E). The final rule creates separate subparts for the specific operations to make it easier to find the relevant production and process control requirements for a particular activity.

Table 1 of this document summarizes how we reorganized the rule. We are providing this information to help readers understand the structural changes we made between the proposed and final rules.

TABLE 1.—REORGANIZATION AND REVISIONS: 2003 CGMP PROPOSAL AND FINAL RULE

Proposed Subpart and Title	Proposed Sections in the Subpart	Final Subpart and Title	Final Sections in the Subpart
A—General Provisions	111.1 111.2 111.3 111.5 111.6	A—General Provisions	111.1 111.3 111.5
B—Personnel	111.10 111.12 111.13	B—Personnel	111.8 (new) 111.10 111.12 111.13 111.14 (new)
C—Physical Plant	111.15 111.20	C—Physical Plant and Grounds	111.15 111.16 (new) 111.20 111.23 (formerly proposed § 111.15(d)(3) and (e)(2))
D—Equipment and Utensils	111.25 111.30	D—Equipment and Utensils	111.25 (formerly proposed § 111.25(c)(1) and (e)(1)) 111.27 (formerly proposed § 111.25 (a), (b), (d)[1], and (e)) 111.30 111.35 (formerly proposed §§ 111.25 (c)(1), (c)(2), (d), (f), 111.30(b)(2), (b)(5), and (c), 111.50(c)(4))

TABLE 1.—REORGANIZATION AND REVISIONS: 2003 CGMP PROPOSAL AND FINAL RULE—Continued

Proposed Subpart and Title	Proposed Sections in the Subpart	Final Subpart and Title	Final Sections in the Subpart
E—Production and Process Controls	111.35 111.37 111.40 111.45 111.50 111.60 111.65 111.70 111.74	E—Requirement to Establish a Production and Process Control System	111.55 (formerly proposed § 111.35(a)) 111.60 (formerly proposed § 111.35(b)) 111.65 (formerly proposed § 111.35(c)) 111.70 (formerly proposed § 111.35(e), (f), (g), and (k)) 111.73 (formerly proposed § 111.35(f), (g), and (h) 111.75 (formerly proposed § 111.35(e) through (i), (k), and (l)), § 111.37(b)(11(iv), and § 111.40(a)(2) 111.77 (new) 111.80 (formerly proposed § 111.37(b)(11)) 111.83 (formerly proposed §§ 111.37(b)(12), 111.50(h), and 111.83(b)(2)) 111.87 (formerly proposed §§ 111.35(i) and (n), 111.37(b)(5) and (b)(14), 111.40(a)(3), 111.50(d)(1), and 111.85(a) and (c)) 111.90 (formerly proposed §§ 111.35(i)(4), 111.50(d)(1), (f), and (g), and 111.65(d)) 111.95 (formerly proposed § 111.35(o))

TABLE 1.—REORGANIZATION AND REVISIONS: 2003 CGMP PROPOSAL AND FINAL RULE—Continued

Proposed Subpart and Title	Proposed Sections in the Subpart	Final Subpart and Title	Final Sections in the Subpart
		F—Production and Process Control System: Requirements for Quality Control	111.103 (new) 111.105 (formerly proposed § 111.37(a), (b)(1), (b)(11), and (b)(12)) 111.110 (formerly proposed § 111.37(b)(9) and (b)(13)) 111.113 (formerly proposed §§ 111.35(i)(2), (i)(3), (i)(4)(i), (i)(4)(ii), (j), and (n), 111.37(b)(3) and (c), 111.40(a)(3) and (b)(2), 111.50(d)(1), 111.65(d), and 111.70(c)) 111.117 (formerly proposed §§ 111.30(b)(4) and 111.37(b)(6) through (b)(8)) 111.120 (formerly proposed §§ 111.35(i)(4)(i) and (i)(4)(ii), 111.37(b)(2) and (b)(10), 111.40(a)(3) and (b)(2), and 111.50(e)(1)) 111.123 (formerly proposed §§ 111.35(e)(2), (f), (i)(2), and (o)(2) 111.37(a), (b)(2), (b)(4), (b)(5), and (b)(11), 111.45(c), and 111.50(d)(1), (d)(2), and (g)) 111.127 (formerly proposed §§ 111.37(b)(2), (b)(10), and (b)(11), 111.40(a)(2) and (a)(3), and 111.70(c), (d) and (e)) 111.130 (formerly proposed §§ 111.37(b)(2) and (b)(15), and 111.85(a)) 111.135 (new) 111.140 (formerly proposed §§ 111.35(j) and 111.37(c) and (d)
		G—Production and Process Control System: Requirements for Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling a Dietary Supplement	111.153 (new) 111.155 (formerly proposed §§ 111.35(d)(1) through (d)(5) and 111.40(a)(1) through (a)(5)) 111.160 (formerly proposed §§ 111.35(e)(4), and 111.40(a)(2) and (b)(1) through (b)(4)) 111.165 (formerly proposed § 111.40(a)(1) through (a)(5)) 111.170 (formerly proposed § 111.74) 111.180 (formerly proposed §§ 111.35(d)(4), and 111.40(c)(1)(i) through (c)(1)(iv) and (c)(2))
		H—Production and Process Control System: Requirements for the Master Manufacturing Record	111.205 (formerly proposed § 111.45(a)(1), (a)(2), and (d)) 111.210 (formerly proposed § 111.45(b))

TABLE 1.—REORGANIZATION AND REVISIONS: 2003 CGMP PROPOSAL AND FINAL RULE—Continued

Proposed Subpart and Title	Proposed Sections in the Subpart	Final Subpart and Title	Final Sections in the Subpart
		I—Production and Process Control System: Requirements for the Batch Production Record	111.255 (formerly proposed § 111.50(a), (b), and (i)) 111.260 (formerly proposed §§ 111.35(i)(2), (j), (m), and (o)(2), 111.37(b)(3), (b)(5), (b)(9) and 111.50(c)(1) through (c)(11), (c)(13), (c)(14), (d)(2), (e), and (g), and 111.70(b)(6) and (g))
		J—Production and Process Control System: Requirements for Laboratory Operations	111.303 (new) 111.310 (formerly proposed § 111.60(a)) 111.315 (formerly proposed § 111.60(b)(1)) 111.320 (formerly proposed § 111.60(c) and (d)) 111.325 (formerly proposed § 111.60(b)(2) and (b)(3))
		K—Production and Process Control System: Requirements for Manufacturing Operations	111.353 (new) 111.355 (formerly proposed § 111.65(a)) 111.360 (formerly proposed § 111.65(b)) 111.365 (formerly proposed § 111.65(c)) 111.370 (formerly proposed § 111.74) 111.375 (new)
		L—Production and Process Control System: Requirements for Packaging and Labeling Operations	111.403 (new) 111.410 (formerly proposed § 111.70(a), (b)(6), and (f)) 111.415 (formerly proposed § 111.70(b)) 111.420 (formerly proposed § 111.70(d) and (e)) 111.425 (formerly proposed § 111.74) 111.430 (formerly proposed § 111.70(g) and (h))
F—Holding and Distributing	111.80 111.82 111.83 111.85 111.90	M—Holding and Distributing	111.453 (new) 111.455 (formerly proposed § 111.80) 111.460 (formerly proposed § 111.82) 111.465 (formerly proposed § 111.83(b)(1) and (b)(2)) 111.470 (formerly proposed § 111.90) 111.475 (new)

TABLE 1.—REORGANIZATION AND REVISIONS: 2003 CGMP PROPOSAL AND FINAL RULE—Continued

Proposed Subpart and Title	Proposed Sections in the Subpart	Final Subpart and Title	Final Sections in the Subpart
		N—Returned Dietary Supplements	111.503 (new) 111.510 (formerly proposed § 111.85(a)) 111.515 (formerly proposed § 111.85(b) and (c)) 111.520 (formerly proposed § 111.37(b)(15)) 111.525 (formerly proposed § 111.50(g)) 111.530 (formerly proposed § 111.85(d)) 111.535 (formerly proposed §§ 111.50(g) and 111.85(e) and (f))
G—Consumer Complaints	111.95	O—Product Complaints	111.553 (new) 111.560 (formerly proposed § 111.95(a) through (d)) 111.570 (formerly proposed § 111.95(e) and (f))
H—Records and Recordkeeping	111.125	P—Records and Recordkeeping	111.605 (formerly proposed § 111.125((a) and (b)) 111.610 (formerly proposed § 111.125(b) and (c))

[1]The reference to (d) is the second (d) in the proposed rule in this section due to a misnumbering in the proposed rule.

We discuss all subparts and sections, and our reasons for amending or creating subparts and sections, in our discussion of the comments to the proposal.

III. What Does the Final Rule Do?

A. Overview of CGMP

In considering the specific requirements necessary for dietary supplement CGMPs, we considered information from a variety of sources. We considered information from our outreach activities, as described in section I of this document; comments to the 2003 CGMP Proposal; our own knowledge and expertise about CGMP for foods, including dietary supplements; and characteristics of CGMP that apply to manufacturing, labeling, packaging, and holding operations.

The general food CGMPs in part 110 (21 CFR part 110) largely address practices designed to ensure that food is manufactured, processed, packed, and held under sanitary conditions and that the food is safe, clean, and wholesome. Although the general food CGMPs in part 110 apply to a variety of food products, including dietary supplements, they do not address the unique characteristics of certain specific types of food products. The agency has implemented separate, and more specific, CGMPs for various types of food products to provide for process controls in manufacturing that are not captured by the more general part 110 food CGMPs. (See discussion in section V of this document (''Legal Authority'') on product specific CGMP requirements). At the time DSHEA was enacted, there were four such additional, specific food CGMP regulations: Those for infant formula (part 106 (21 CFR part 106)), thermally processed low-acid canned food (part 113 (21 CFR part 113)), acidified food (part 114 (21 CFR part 114)), and bottled water (part 129 (21 CFR part 129)).

Dietary supplements are a type of food product for which specific food CGMPs also are needed. Manufacturing process controls are needed to ensure that a dietary supplement contains what the manufacturer intends. Unlike most foods, the majority of dietary supplements are packaged into tablets, gelcaps, and capsules. Some dietary supplements may contain bioactive ingredients for which certain, controlled amounts are intended to be in each tablet or capsule. The process controls that must be in place to ensure the tablet or capsule contains what it purports to contain are different than those that must be in place to ensure a food is manufactured, processed, packed, and held under sanitary conditions. Process controls for dietary supplement manufacture include establishing and meeting specifications to ensure the finished dietary supplement contains the correct ingredient, purity, strength, and composition intended.

Vitamins can present a concentrated source of biologically active components. A vitamin, for example, that contains too high a concentration, such as vitamin D at levels that are many times greater than intended, can lead to illness and hospitalization (Refs. 7 and 8). A manufacturer must establish a process for manufacturing a dietary supplement product in order to produce the product consistently and reliably each time. In order to achieve consistency and reliability, there must be process controls in place to ensure, for example, that appropriate tests and examinations are conducted, a master manufacturing record is prepared, each batch production follows the master manufacturing record, and the finished tablet or capsule is placed in the intended package with the intended label.

These same types of controls are needed for herbal and botanical dietary supplements. Botanicals are often complex mixtures that can vary in

composition depending on factors such as the part of the plant used, the location of harvesting and growing conditions that can vary from year to year even in the same location. It can be difficult to distinguish between closely related species of botanicals, and the biological activity of components of an incorrectly identified species can lead to adverse consequences. In addition, different species may be present in different ratios or blends in a particular product. Various products might contain different parts of the plant—flower, leaf, root, stem, extract—and the test methods for each can vary in the nature, sensitivity, and specificity of the test.

Well-established principles of CGMP require process controls at each step of the manufacturing process as early in the production process as possible. Quality cannot be tested into the product only at the end (Ref. 9). Instead, the quality of the dietary supplement must be built into the product throughout the manufacturing process; quality begins with the starting material and continues with the product being manufactured in a reproducible manner according to established specifications. It is not sufficient, nor effective, to rely solely on end product testing to assure the quality of the individual dietary supplement product sold to the consumer.

CGMPs are intended to establish a comprehensive system of process controls, including documentation of each stage of the manufacturing process, that can minimize the likelihood of, or detect, problems and variances in manufacturing as they occur and before the product is in its finished form. These process controls that are a part of CGMPs are essential to ensure that the dietary supplement is manufactured, packaged, held, and labeled in a consistent and reproducible manner.

Manufacturing according to CGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a quality finished product. CGMPs specific to dietary supplements are necessary to help ensure that these products have the identity, purity, strength, and composition that meet specifications established in the master manufacturing record and that they are not adulterated.

Many comments stressed that the most critical aspect of a successful CGMP system is effective process control. Comments asserted that, with effective process control, quality is built into a product throughout the entire production process. The term ''quality'' came up repeatedly in comments as the desired outcome of the dietary supplement manufacturing process.[1] In fact, several comments asked us to define ''quality'' and suggested various definitions, each of which related to a dietary supplement having the identity, purity, strength, and composition intended (see comment 49 in section VI of this document). Some comments distinguished the concept of quality from that of preventing adulteration. These comments objected to our statement that dietary supplement CGMP requirements are needed to prevent adulteration and stated that CGMP is focused on assuring that finished products are manufactured using quality procedures, but are not related to preventing adulteration. Other comments asked us to define ''adulteration.''

We agree that a critical aspect of CGMP is achieving control over manufacturing processes. Controls are necessary to ensure that you manufacture what you intend so that the characteristics and/or attributes desired in a final product will be consistently and reliably achieved. We disagree with the comments to the extent that they were suggesting that quality is not related to preventing contamination in the manufacturing process that may adulterate the finished product. However, we have reconsidered, as discussed in this section, what types of adulteration and misbranding are necessary to control for in this dietary supplement CGMP rule.

To clarify what dietary supplement CGMP requirements are intended to achieve, we have added a definition of quality in the final rule. As defined, quality means ''that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the Federal Food, Drug, and Cosmetic Act.'' Ensuring the quality of the dietary supplement means that you consistently and reliably manufacture what you intend and that you establish manufacturing controls to prevent the dietary supplement from being adulterated under section 402(a)(1) of the act due to the presence of contaminants, under section 402(a)(2) of the act, for example, if it bears or contains any unintentionally added poisonous or deleterious substance, under section 402(a)(3) of the act if the dietary supplement consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food, or under section 402(a)(4) of the act if the dietary supplement has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The definition of quality limits to section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act the types of adulteration that you must control for in this CGMP final rule. The definition applies to the controls that are designed to prevent contamination of the product that you intend to manufacture.

In the 2003 CGMP Proposal, we said that our purpose was to present a broad enough scope to the proposed rule so that we could receive the depth and breadth of comment needed to develop a final rule that would provide the proper balance of regulation (68 FR 12157 at 12161). We asked for comment on whether each of the provisions proposed was necessary to ensure the safety and quality of the dietary supplement and was adequate to protect the public health (id.). We stated that the proposed rule ''would establish the minimum CGMPs necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements'' (68 FR 12157 at 12158). For example, we stated that the proposed rule would require the manufacturer to test for toxic compounds in botanicals that may likely be present to ensure that no such compounds are present that may adulterate the dietary supplement (68 12157 FR at 12162). Further, we included a requirement that the ingredients, other than dietary ingredients under section 201(ff) of the act, be lawful under the applicable food additive regulations or be generally recognized as safe (GRAS) (proposed § 111.35(d).

The approach that we set forth in the 2003 CGMP Proposal was designed to prevent a manufacturer, under CGMP regulations, from using an ingredient, whether a dietary ingredient or another

[1] Throughout this final rule, we refer to the ''manufacture'' or ''manufacturing process'' of dietary supplements. We use these terms in the broad sense, i.e., the terms refer to those activities that may be done from receipt of raw ingredients through the distribution of a finished dietary supplement, including labeling, packaging, and holding activities. We discuss the various roles and responsibilities of those who ''manufacture'' dietary supplements in the context of final § 111.1 ''Who is subject to this part?'' We also sometimes use the terms to apply to only part of the process, i.e., those operations other than labeling, packaging, and holding.

component, in the manufacture of a dietary supplement that would adulterate the product under relevant provisions of the act, such as section 402(a)(1) or (a)(2)(C). The manufacturer would have been required to establish specifications at any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration (proposed § 111.35(e)). Thus, the manufacturer would not have been able to establish a specification, consistent with proposed § 111.35(e), for the use of an unlawful ingredient because such use would not prevent adulteration. In addition, the manufacturer would have to establish specifications for contaminants that may adulterate or that could lead to adulteration of the dietary supplement. The manufacturer would have to take necessary precautions to prevent the presence or level of contaminants, that would otherwise adulterate the dietary supplement under another provision of the act, from being present in the dietary supplement. The specifications were intended to ensure that adulterated and misbranded dietary supplements would not reach the marketplace (68 FR 12157 at 12197).

In addition to the general specifications established under proposed § 111.35(e), the proposed rule would have required the manufacturer to establish specifications for the identity, purity, quality, strength, and composition of the components received (proposed § 111.35(e)(1)) and for the finished batch of dietary supplement (proposed § 111.35(e)(3)). Although we stated that the proposed rule did not address questions related to the safety of dietary ingredients used (68 FR 12157 at 12172), if a dietary ingredient was deemed to be unsafe under the act—under section 402(a)(1) or another provision—a specification could not have been established for that dietary ingredient, consistent with proposed § 111.35(e). Thus, a manufacturer would not be able to use, under dietary supplement CGMP, a dietary ingredient, or other component, that would otherwise adulterate the product under another provision of the act.

Further, the proposed rule was designed to ensure that the correct label was applied during manufacture so that the dietary supplement label would accurately identify the dietary supplement (proposed §§ 111.45(b)(7), 111.50(c)(12), and 111.70(b)(7)). The proposed rule also would have required the master manufacturing record to contain the identity of each ingredient that is required to be declared on the ingredient list in section 403 of the act (21 U.S.C. 343) (proposed § 111.45(b)(4)).

Several comments seemed to question why the dietary supplement CGMP rule would require that a manufacturer use lawful ingredients when other provisions of the act would require such use. In fact, some comments objected to the proposed requirement in the rule that required that a component, other than a dietary ingredient, be approved for use as a food additive or be GRAS. The comments stressed that such a provision was not necessary because the statute already requires that such an ingredient be approved as a food additive or be GRAS. In light of these comments, we reconsidered our interpretation of the scope of ''prevent adulteration'' in the proposed rule and whether that interpretation should be narrowed. We also considered whether to require, as part of a CGMP requirement, that the label that accurately reflects the ingredients in the product be applied or whether such a requirement was not necessary, given our existing authority in section 403 of the act.

We determined that ensuring quality in dietary supplement CGMP, in part, means that you produce what you intend to produce. As stated in section V of this document, manufacturers must plan what they intend to produce, institute adequate controls to achieve the desired outcome, and ensure that the controls work so that the desired outcome is consistently achieved. Thus, for example, the manufacturer decides on the identity, purity, strength, and composition of the dietary supplement it manufactures. The focus of CGMP is on process controls to ensure that the desired outcome is consistently achieved, and not on the inherent safety of the ingredients used (which is addressed by other statutory prohibitions).

We agree with the comments that the safety of a particular ingredient is governed by other provisions of the act. If you manufacture a dietary supplement, you have a responsibility as a manufacturer to evaluate the safety of the ingredients under, for example, section 402(f) of the act.[2] Dietary supplement CGMP would require you to establish the identity, purity, strength, and composition specifications for the product and ensure that such specifications are met in the finished batch of dietary supplement. Nothing in the dietary supplement CGMPs relieves manufacturers from complying with any other substantive provisions of the act relating to the safety of ingredients and other components.

Quality not only means that you produce what you intend, but that you prevent contamination in your manufacturing process that could adulterate your product. Food CGMP regulations, after which the dietary supplement CGMP rule is modeled, require that the manufacturer take precautions to ensure that the manufacturer does not adulterate the product under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act. For example, under § 110.5 (food CGMP), the criteria and definitions apply in determining whether a food is adulterated under section 402(a)(3) and (a)(4) of the act. Specifically, § 110.80(a)(2) states that raw materials shall not contain levels of microorganisms that may produce food poisoning or other disease in humans, unless otherwise treated during manufacturing operations so that they no longer contain levels that would adulterate the product within the meaning of the act. In addition, § 110.80(a)(3) states that raw materials and other ingredients susceptible to contamination with natural toxins must comply with current FDA regulations and action levels for poisonous or deleterious substances before such materials are incorporated into finished food. Under dietary supplement CGMP, we believe it is appropriate to require you to establish specifications that are designed to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act from contamination during the manufacturing, packaging, labeling, and holding operations. For example, if you are manufacturing a dietary supplement that you know is likely to contain a contaminant, you would need to establish limits on the contaminant in your supplement, and you must design these limits to prevent the dietary supplement from being adulterated under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

Quality, as the term is used for the purposes of this final rule, relates both to producing what is intended (i.e., establishing and ensuring that specifications for the identity, purity, strength, and composition are met) and to ensuring that the dietary supplement that you intend to produce has been manufactured, packaged, labeled, and held under conditions to prevent adulteration within the meaning of section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act. Thus, this final rule is not designed to specifically prevent all

[2] Under section 402(f) of the act, a dietary supplement is deemed to be adulterated if it is or contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling or, if no such conditions, under ordinary conditions of use.

types of adulteration that may occur under the act. Rather, this final rule is designed to prevent adulteration from those types of contamination that are commonly controlled in other food CGMP regulations. We do expect, however, that compliance with CGMP requirements in the final rule will help to avoid other types of adulteration. Also, nothing in this rule exempts a manufacturer from compliance with other relevant adulteration provisions of the act.

We are replacing the phrase ''prevent adulteration'' in the codified with words that relate to ensuring the quality of the dietary supplement. Thus, for example, we have modified proposed § 111.35(e) (now final § 111.70(a)) to read, ''You must establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the finished dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record'' instead of ''* * * necessary to prevent adulteration.'' This phrase is replaced in several codified provisions and an explanation of this change is not provided in the preamble of this document each time it is made.

Moreover, you have a responsibility under CGMP to ensure that the label you specify in the master manufacturing record is applied to the product. Under section 403 of the act, you are required to ensure that your label accurately reflects the ingredients in the product. Because section 403 of the act provides that food, including dietary supplements, is misbranded if a label that does not contain accurate statements is applied, we do not need to impose the same requirement in this final rule. Thus, if the representative label in the master manufacturing record for the product does not identify the correct dietary ingredients and the label that lists inaccurate information is applied, that dietary supplement would be misbranded under section 403 of the act. Such labeling would not be a violation of dietary supplement CGMP unless there is a mixup in your process control and you do not put the representative label specified in the master manufacturing record on the product. Such a mixup would be a violation of dietary supplement CGMP requirements (see e.g., final §§ 111.127(d), 111.160(e), 111.410(c), 111.415).

Thus, in addition to stating ''ensure the quality of the dietary supplement,'' in the codified instead of ''prevent adulteration,'' we are adding the language ''and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.'' Such change is intended to clarify that the use of the packaging and labeling that is stated in the master manufacturing record is what is required in this final rule.

A failure to follow the requirements in this final rule, including a failure to establish required specifications, could result in an enforcement action by the agency under section 402(g) of the act because the dietary supplement is adulterated in that it was prepared, packed, labeled, or held under conditions that do not meet CGMPs for dietary supplements. The act establishes certain prohibited acts and enforcement mechanisms to remove adulterated product from the market and prevent manufacturers from continuing to manufacture adulterated product. Enforcement mechanisms currently available to us under the act are not affected by this final rule.

Finally, we have included in this final rule the existing requirements in part 110 that we believe are common to dietary supplement manufacturing. For example, the requirements in subpart C, *Physical Plant and Grounds*, are similar to those in § 110.20. We recognize that there may be operations related to the manufacturing of dietary supplements for which certain provisions in part 110 apply, but that we did not determine to be common to most dietary supplement manufacturing operations. For example, there may be some dietary supplements that are dehydrated and rely on the control of moisture consistent with § 110.80(b)(14). A manufacturer would be expected to comply with the regulations in part 110 in addition to the regulations in part 111, unless the regulations conflict. To the extent that the regulations conflict, the dietary supplement manufacturer must comply with the regulation in part 111.

B. Highlights of the Final Rule

The final rule:

- Applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1;
- Establishes minimum requirements for personnel, physical plant and grounds, and equipment and utensils;
- Requires the establishment and use of written procedures for certain operations, including those related to equipment, physical plant sanitation, certain manufacturing operations, quality control, laboratory testing, packaging and labeling, and product complaints;
- Requires the establishment of specifications in the production and process control system that will ensure dietary supplements meet the identity, purity, strength, and composition established in specifications and are properly packaged and labeled as specified in the master manufacturing record;
- Provides for the option to use a certificate of analysis (for specifications other than the identity of a dietary ingredient) from a component supplier instead of having manufacturers conduct tests or examinations on the components they receive;
- Requires testing of a subset of finished batches of dietary supplements based on a sound statistical sampling or, alternatively, testing all finished batches;
- Requires implementation of quality control operations to ensure the quality of a dietary supplement;
- Requires the preparation and use of a written master manufacturing record for each unique formulation of manufactured dietary supplement, and for each batch size, to ensure your manufacturing process is performed consistently and to ensure uniformity in the finished batch from batch to batch;
- Requires the preparation of a batch production record every time a dietary supplement batch is made. The batch production record must accurately follow the appropriate master manufacturing record;
- Requires the establishment and use of laboratory control processes related to establishing specifications and to the selection and use of testing and examination methods;
- Requires reserve samples of dietary supplements to be held in a manner that protects against contamination and deterioration;
- Requires identification and quarantine of returned dietary supplements until quality control personnel conduct a material review and make a disposition decision;
- Requires quality control personnel to conduct a material review and make a disposition decision under certain circumstances;
- Requires a qualified person to investigate any ''product complaint'' that involves a possible failure of a dietary supplement to meet any CGMP requirement, with oversight by quality control personnel; and
- Requires records associated with the manufacture, packaging, labeling, or holding of a dietary supplement to be kept for 1 year beyond the shelf life dating (when such dating is used, such as expiration dating, shelf life dating, or ''best if used by'' dating), or if shelf life dating is not used, for 2 years beyond the date of distribution of the last batch

of dietary supplements associated with those records.

IV. What General Comments Did We Receive?

We received approximately 400 comments on the proposed rule. Although most comments support CGMP requirements for dietary supplements and dietary ingredients, others question the need for a regulation and many sought changes to the rule. We describe, in this section, comments on general aspects of the final rule. We include comments related to the structure and organization of the final rule, comments we received on why CGMP requirements are needed, and comments on written procedures. In addition, we describe some general comments we received on multiple sections of the proposed rule that we believe are better addressed in one response.

To make it easier to identify comments and our responses, the word ''comment,'' in parentheses, will appear before each comment, and the word ''response'' will appear before each response. We also have numbered the comments to make it easier to distinguish between comments; the numbers are for organizational purposes only and do not reflect the order in which we received the comments or any value associated with the comment.

A. What Comments Did We Receive on the Structure and Organization of the Rule?

(Comment 1) Several comments seek to restructure or reorganize the rule. For example, one comment states we should simplify the entire section on production and process controls. The comment asserts it would be more logical to list contaminants that may adulterate a dietary supplement or lead to adulteration as part of the requirements for specifications (proposed § 111.35(e)) than to list such contaminants as part of the testing requirements (proposed § 111.35(k)). Other comments say it would be more logical to list the tests that are considered appropriate as part of proposed § 111.35(h) (concerning appropriate tests or examinations to determine whether specifications are met) than to have a separate requirement for appropriate tests in proposed § 111.35(l) (which listed the types of analyses that should be part of a test).

Another comment claims the rule is too complex, asserting it would create chaos. Other comments say that the proposal's degree of detail required is unrealistic for small dietary supplement firms, and we should rewrite the rule to be more user friendly.

Yet another comment says that any final rule we issue must clearly set forth CGMP requirements. This comment seems to suggest the requirements need to be more detailed in describing what is required. The comment asserts that ambiguities in interpretation could result in economic disadvantage for small businesses because they typically do not have in-house legal counsel and, thus, must be more conservative in interpreting ambiguous regulatory provisions.

(Response) In response to these comments, as well as comments on specific subparts and provisions, we have reorganized the final rule and have re-phrased or introduced concepts in a ''user-friendly'' or plain language format. We also have eliminated certain redundant regulatory requirements and combined similar requirements. For example, rather than put all production and process control system requirements in a single subpart, we have reorganized the final rule to create a series of subparts that first describe the requirements for the overall design and implementation of the production and process control system and then describe the requirements of the individual operations associated with that system. We also present each requirement as a question rather than as a paragraph within a section. This question format will help readers focus on the subparts or sections that apply to specific operations.

As another example, we reduced the redundancy associated with the interrelated nature of the proposed rule by combining most similar requirements. Both proposed §§ 111.35(m) and 111.60(b)(2) would require you to keep testing and examination results. The final rule places this requirement in a single section (§ 111.325(b)(2)(ii)).

The final rule also shortens the construction ''includes, but is not limited to'' to ''includes.'' We did this because the use of the word ''includes'' indicates that the specified list that follows is not exclusive. The phrase ''but is not limited to'' is unnecessary.

Finally, some changes we have made to one specific section have an impact on other sections. For example, after considering the comments, we revised subpart B to require you to establish and follow written procedures to fulfill the requirements of subpart B. Those written procedures are records you must make and keep in accordance with the recordkeeping requirements of subpart P, thus we made changes to include that requirement of making and keeping records.

B. What Comments Did We Receive on the Need for Dietary Supplement CGMP Requirements?

(Comment 2) Some comments state that dietary supplement CGMP requirements will protect consumers from supplements that contain inherently unsafe dietary ingredients. Other comments request that we take additional action to ensure the safety of dietary ingredients.

(Response) This final rule focuses on the manufacturing practices of dietary supplements and not on whether certain dietary ingredients are or are not safe. Therefore, comments related to whether certain dietary ingredients are inherently unsafe and any request to take actions related to the inherent safety of dietary ingredients are outside the scope of this rule.

(Comment 3) Some comments support the rule, explaining that it will address current problems with superpotent and subpotent dietary supplements, undeclared ingredients, and varying levels of ingredients. Others indicate the rule will better protect consumers and increase consumer confidence. One comment states that CGMP requirements for dietary supplements are not needed for responsible manufacturers because they already manufacture safe dietary supplements. Some comments state that dietary supplement CGMP requirements are not needed because the dietary supplements have a track record of safety. Other comments say there were more adverse events reported from drug use than from dietary supplement use and that a large number of Americans take dietary supplements, and on that basis suggested that dietary supplements are safer than foods or drugs.

(Response) We agree the final rule will better protect consumers and help address the types of manufacturing problems identified in the preamble to the 2003 CGMP Proposal (see 68 FR 12157 at 12162 through 12163) through consistent use of established production processes and controls.

However, we disagree with the comments asserting dietary supplements have a track record of safety such that dietary supplement CGMP requirements are unnecessary. Section 402(g) of the act does not require us to establish a ''bad'' track record of safety in the manufacture of dietary supplements before we may issue a dietary supplement CGMP rule. Furthermore, we disagree with the comments comparing dietary supplement safety to drug safety; there

are different statutory requirements, different regulatory requirements, and different safety evaluations for dietary supplements and drugs.

We also disagree that the final rule should apply only to manufacturers who cannot manufacture dietary supplements responsibly. Establishing who is or is not a responsible manufacturer is not a threshold requirement in section 402(g) of the act, and it would be impractical to regulate dietary supplement CGMP in such a manner, because parties may differ as to whether a particular manufacturer acted ''responsibly'' in a particular situation. All dietary supplement manufacturers are subject to this final rule, just as all dietary supplement manufacturers are subject to section 402(g) of the act. We therefore are not persuaded that dietary supplement CGMP requirements are not needed, or should only be applied to manufacturers who have not acted ''responsibly.''

(Comment 4) Some comments state that our authority under the current food CGMP regulation in part 110 and our authority to take actions against adulterated and misbranded products generally are sufficient. Other comments state that DSHEA gives us the necessary legal authority to protect the public health and that additional regulatory requirements are unnecessary. Several comments object to our statement that dietary supplement CGMP requirements are needed to prevent adulteration. These comments suggest dietary supplement CGMP is focused on ensuring finished products are manufactured using quality procedures, but are not related to preventing adulteration. Other comments state we should enforce current food CGMP regulations rather than adopt new regulations.

(Response) We disagree that dietary supplement CGMP requirements are not related to preventing adulteration. In fact, under the statutory scheme a dietary supplement is deemed to be adulterated under section 402(g)(1) of the act if it fails to meet CGMP requirements we promulgate by regulation. As we discussed in section III of this document, dietary supplement CGMP requirements are necessary to ensure the quality of the dietary supplement; ensuring quality includes ensuring that the dietary supplement has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

We also disagree with those comments stating that the requirements in part 110 are adequate and that no additional requirements are necessary. The comments do not explain why the specific requirements set forth in the proposed rule that are not also in part 110 are unnecessary. As discussed in greater detail in response to comments on our legal authority in section V of this document, the particular characteristics and hazards of dietary supplements call for CGMP requirements tailored to dietary supplements. Congress specifically provided independent authority under section 402(g) of the act for us to promulgate CGMP requirements for dietary supplements. That authority would have been unnecessary if Congress had concluded that part 110 was adequate.

We also disagree that enforcement of part 110 would eliminate a need for dietary supplement CGMP requirements. The dietary supplement CGMP requirements include practices specifically tailored to the characteristics and hazards of dietary supplements and their manufacturers. The comments asserting that current food CGMP requirements in part 110 are sufficient provided no persuasive or compelling reasons for that assertion, or for why we should not implement dietary supplement CGMP requirements under section 402(g) of the act. For these reasons, we are not persuaded by the comments that these dietary supplement CGMP requirements are not needed.

(Comment 5) Some comments object to the examples of manufacturing problems that we used to support the need for CGMP requirements. Specifically, some comments object to the *Prevention* magazine citation and also object to the nine examples we presented in the preamble to the 2003 CGMP Proposal (see 68 FR 12157 at 12161 through 12163). We cited the *Prevention* magazine survey on consumer use of dietary supplements to show that only 41 percent of surveyed consumers who use vitamins and minerals think those products are very safe, and only 50 percent think the products are somewhat safe; among those using herbal products, only 24 percent thought the products were very safe, and only 53 percent thought the products were somewhat safe. We noted that 74 percent supported increased government regulation of dietary supplements (see, id.). As one example of adulterated dietary supplements caused by manufacturing practices, the preamble to the 2003 CGMP Proposal mentioned an instance where a young woman suffered a life-threatening abnormal heart function that was traced to a mislabeled or contaminated dietary ingredient (68 FR 12157 at 12162). Another example involved recalls of super- and subpotent dietary supplements (id.).

Comments objecting to the *Prevention* survey said it provided no rationale for why CGMP requirements are needed. Other comments said the nine examples we provided represent a failure to conform to an existing regulation and do not demonstrate a need for a new CGMP regulation for dietary supplements. One comment disagrees that the CGMP requirements would prevent adverse reactions, as one example suggested in the preamble to the 2003 CGMP Proposal (see 68 FR 12157 at 12162) because, the comment claims, most adverse reactions are not the result of manufacturing problems. Another comment states the example involving plantain (68 FR 12157 at 12162), where a raw material was labeled as ''plantain'' when it was, in fact, *Digitalis lanata* (a plant that can cause life-threatening heart reactions), shows that, had there been a system in place to test finished product for purity and identity or to perform identity testing upon receipt, the manufacturer could have prevented that adulterated product from entering the market place. The comment states identity testing is necessary in the final rule.

Another comment objects to the example of ''non-food grade chemicals'' (id.) because the reference supporting the example involved Gamma-Butyrolactone, a substance we have stated is an unapproved new drug and not a dietary supplement. Some comments say the risks cited in the justification for these regulations are hypothetical or theoretical and current statutory or regulatory authority is adequate.

(Response) We disagree, in most part, with the comments. We cited the *Prevention* survey to illustrate consumer perception and support for increased government involvement in dietary supplement regulation. We did not describe the survey as illustrating CGMP problems associated with dietary supplements.

We also disagree that the risks cited in the preamble to the 2003 CGMP Proposal are merely hypothetical or theoretical. We provided actual examples of failures in the manufacturing of products marketed as dietary supplements. The comments may have misunderstood what the CGMP requirements for dietary supplements are intended to accomplish. A principal goal of the CGMP requirements is to have those who manufacture, package, label, or hold dietary supplements do so in a manner that ensures the quality of the

dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. It is the manufacturer who needs to establish procedures for its manufacturing operations to ensure, for example, the final product is produced according to its specifications in the master manufacturing record, meets limits on contaminants, and is a quality dietary supplement. If a product does not meet its specifications, a manufacturer who observes the CGMP requirements should know that and be able to take corrective action before the dietary supplement enters the marketplace. The onus is on the manufacturer, and not simply on us, to take action to prevent the adulterated product from entering the market or, if the product has already been released, to remove the product from the market. The umbrella food CGMP requirements in part 110 do not contain specific provisions establishing specifications, requiring identity testing, or requiring in-process and/or finished product testing. Through this final rule, we are establishing a new CFR part regarding CGMP requirements specifically for dietary supplements.

The examples we used in the preamble to the 2003 CGMP Proposal included adverse event reports associated with contamination with *Digitalis lanata*, the possible contamination of botanical ingredients with toxic compounds, the use of non-food grade chemicals, the manufacture of super- and subpotent dietary supplements, the presence of undeclared ingredients, and the variability of ingredients from what is declared on the label (Refs. 7, 8, and 10; see, also, 68 FR 12157 at 12162 through 12163). These were all examples where products were manufactured, labeled, and sold to the consumer as dietary supplements. We disagree with the comments' assertions that all these problems can be adequately dealt with by the food CGMP requirements in part 110, but agree with the comment that, had there been a system in place ''to perform identity testing upon receipt, the manufacturer could have prevented that adulterated product from entering the market place.'' Most of these examples present situations in which the manufacturer could have identified these problems through the dietary supplement CGMP requirements for specifications and testing or examination, such as identity verification, and could have prevented such products from entering the market or at least provided a greater assurance that such products would not make it into the marketplace. The dietary supplement CGMP requirements ensure adequate controls are in place to identify many of these types of manufacturing errors before the product is in the marketplace and not through postmarketing adverse event reports or consumers' illnesses.[3]

The dietary supplement industry is diverse, as are the number and types of products marketed as dietary supplements. As we stated in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12163), given the wide range of public health concerns presented by the manufacturing practices for dietary supplements, a comprehensive system of controls is necessary. This final rule will set the standards for CGMP for dietary supplements that, if followed, will help ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. The establishment of production and process controls and adherence to these and other CGMP requirements of this final rule will help to prevent the types of events (and others) we described in the nine examples presented in the preamble to the 2003 CGMP Proposal.

(Comment 6) Several comments suggest that dietary supplements are no different in safety or physiologic effect and require no different requirements than conventional food with respect to CGMP. One comment disagrees with us that dietary supplements require different requirements than conventional food because dietary supplements are ground up or in powder form and may not be easily recognized or differentiated; the comment says the same is true of many food ingredients as well.

(Response) We disagree with the suggestions by these comments that dietary supplement CGMP requirements need not differ from those for conventional foods. By definition, a dietary supplement is in a category of food separate and distinct from the category of conventional food. The definition of dietary supplement in section 201(ff) of the act, in part, essentially describes a dietary supplement as a type of food that differs from conventional food. The definition refers to section 411(c)(1)(B)(i) and (c)(1)(B)(ii) of the act (21 U.S.C. 350(c)(1)(B)(i) and (c)(1)(B)(ii)), which describes the forms that dietary supplements intended to be ingested may take, i.e., tablet, capsule, powder, softgel, gelcap, or liquid form, and if not in such a form, limitations on how dietary supplements can be represented, i.e., not as conventional food or as a sole item of a meal or the diet.

Congress included separate additional provisions under section 402 of the act (see section 402(f) and (g) of the act) for when a dietary supplement may be adulterated. Congress considered that dietary supplements may warrant CGMP requirements that are different than those for conventional food. Although dietary supplements may include substances that are used as ingredients in conventional foods, the amounts consumed as a dietary supplement and as a conventional food product may not be the same and, in fact, may be more concentrated, and in higher amounts, when taken as a dietary supplement. The forms in which dietary supplements are consumed differ (e.g., capsule, tablet), as may the frequency, when compared to conventional foods. The uses of dietary supplements also differ from use as conventional food. Consequently certain manufacturing practices considered to be a part of CGMP for dietary supplement manufacturing may not be necessary for all types of food.

C. What Comments Did We Receive on Written Procedures?

1. Overview

In the 2003 CGMP Proposal (68 FR 12157 at 12165), we stated that written procedures were included in the dietary supplement CGMP outline submitted to us by industry, namely, the National Nutritional Foods Association standards (NNFA), the NSF International draft standards, and the United States Pharmacopoeia (USP) draft manufacturing practices. We also stated that, to limit the burden to manufacturers, we were not proposing to require written procedures for all the requirements. We invited comment on whether we should require written procedures for a variety of operations; specifically, for complying with the CGMP requirements, under proposed § 111.10 for personnel hygiene and for preventing microbial contamination due to personnel (68 FR 12157 at 12182); maintenance, cleaning, and sanitation for the physical plant under proposed § 111.15 (68 FR 12157 at 12187); calibrating instruments and controls under proposed § 111.25(b), (c), and (d) (68 FR 12157 at 12191); maintaining, cleaning, and sanitizing equipment and utensils under proposed § 111.25(e) (68

[3]Mandatory reporting to FDA of serious adverse events is now required as a result of the enactment of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462) signed into law on December 22, 2006 (see discussion in section XX of this document).

FR 12157 at 12192); calibrating, inspecting, and checking automatic equipment under proposed § 111.30 (68 FR 12157 at 12193); the duties of the quality control unit under proposed § 111.37 (68 FR 12157 at 12201); implementing the proposed requirements for receipt of components, dietary supplements, packaging, and labels under proposed § 111.40(a) and (b) (68 12157 at FR 12203); preparing the master manufacturing record under proposed § 111.45 (68 FR 12157 at 12205); laboratory operations under proposed § 111.60 (68 FR 12157 at 12209); manufacturing operations under proposed § 111.65 (68 FR 12157 at 12211); packaging and labeling operations under proposed § 111.70 (68 FR 12157 at 12213); holding components, dietary supplements, packaging, labels, and in-process materials under proposed §§ 111.80 and 111.82 (68 FR 12157 at 12214); identifying, quarantining, and salvaging returned dietary supplements under proposed § 111.85 (68 FR 12157 at 12216); and receiving, reviewing, and investigating consumer complaints under proposed § 111.95 (68 FR 12157 at 12217).

We stated that if comments assert that written procedures are necessary, comments should include an explanation of why the requirement is necessary to prevent adulteration including how such a requirement would ensure the identity, purity, quality, strength, and composition of the dietary supplement. Conversely, if comments assert that written procedures are not necessary, we asked for an explanation of why and how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary supplement.

(Comment 7) Many comments stress the most critical aspect of a successful CGMP system is effective process control, which requires conducting key operations using written procedures. Several comments assert that written procedures are an important part of manufacturing operations to ensure uniform practices in production operations, from receiving through final operations. Several comments assert written procedures provide a sound basis for employee training and supervision. Several comments state that without a written training program, it is very likely that some employees may not receive sufficient training, or in some cases, any CGMP training at all. One comment specifically suggests that companies develop written procedures for the minimum CGMP training common to all departments.

One comment points out that all well-recognized quality systems require establishment of written procedures to ensure consistent process control, and cites examples such as the International Organization for Standardization, the American National Standards Institute (ANSI), and the Malcolm Baldridge National Quality Award criteria. Other comments state that written procedures are necessary for the definition, operation, and documentation of a process control system, and that without such procedures it would be virtually impossible for any company, regardless of size, to consistently manufacture products that meet established requirements for identity, purity, quality, strength, and composition. The comments note that written procedures contain the necessary instructions for all employees to successfully execute their respective functions. Another comment supports a requirement for conducting key operations using written procedures and states that records document that operations were performed, but that written procedures show how the task is to be performed and at what frequency it should be performed. One comment states effective communication is essential to build quality into a process, and written procedures provide that throughout all levels of an organization. Another comment states it is difficult to imagine how the quality control unit could carry out its obligations under proposed § 111.37(b)(1) to ''approve or reject all processes, specifications, controls, tests, and examinations, and deviations from or modifications to them * * *'' if these are not subject to written procedures.

Many comments which present one or more of these general reasons for requiring written procedures also list operations that they believe should be conducted using written procedures. The operations that one or more comments list as key operations are:

- Employee training;
- Cleaning the physical plant, including pest control;
- Maintenance, cleaning, and sanitizing of equipment and utensils;
- Calibration of equipment used in manufacturing or testing;
- All aspects of the production process, including a general procedure to document the minimum investigation, review, and approval requirements for failures in manufacturing or packaging operations;
- All quality control operations;
- Reprocessing of batches or start-up materials that do not conform to specifications;
- Receipt, identification, examination, handling, sampling, testing, and approval or rejection of components, packaging, and labels;
- Laboratory operations, including the establishment of specifications and descriptions of laboratory test methods used to ensure that components, in-process materials, and finished product meet established specifications;
- Packaging and labeling operations, including issuance and use of appropriate labels, labeling, and packaging materials;
- Holding and distribution procedures, including procedures for quarantine and parameters for storage;
- Return and salvage operations;
- Handling of consumer complaints; and
- Procedures for product recall.

Many comments assert an effective process control system that includes extensive written procedures would justify a decreased testing burden with respect to the finished product. One comment suggests we exempt manufacturers from the requirement to test each finished batch of product if they have a qualified manufacturing process that meets certain basic criteria, including a requirement for written procedures for each stage of the process. One comment notes it would be clearer to all parties if specific written procedures were listed as required and stresses the importance of having all companies know exactly what is procedurally expected of them.

In addition to these general reasons for requiring that key operations be conducted using written procedures, several comments provide specific reasons for requiring that specific operations be conducted using written procedures. In response to our request for comment on whether written procedures should be required for complying with proposed § 111.10 (personnel hygiene and for preventing microbial contamination due to personnel), one comment states that written procedures help to ensure compliance with the proposed hygiene requirements by clearly listing the requirements and requiring the employees to follow them on a consistent basis.

In response to our request for comment on whether written procedures should be required for complying with the proposed requirements for maintenance, cleaning, and sanitation for the physical plant under proposed § 111.15, one comment states that having written procedures in place to clean the physical plant will ensure that there is no cross-contamination. Another comment states utility areas such as effluent treatment, boilers, cooling towers, and water

treatment plants also should have documented procedures for cleaning in order to create a general awareness of cleanliness throughout the plant. Other comments state that such written procedures should not be required because they would not directly prevent contamination or ensure the identity, purity, quality, strength, and composition of the dietary supplement if, as the ''bottom line,'' a manufacturer maintains the physical plant in a clean and sanitary condition.

Responding to our request for comment on whether written procedures should be required for complying with the proposed requirements for calibrating instruments and controls under proposed § 111.25(b), (c), and (d), several comments assert we should require manufacturers to establish and follow written procedures for calibrating equipment and controls. According to these comments, such procedures would provide us with a written record that is sufficient to evaluate the adequacy of the company's calibration procedures and would provide the necessary controls to meet the underlying intent of the rule. These comments assert that written procedures will lessen the risk that adulterated products will be produced.

In response to our request for comment on whether written procedures should be required for complying with the proposed requirements for maintaining, cleaning, and sanitizing equipment and utensils under proposed § 111.25(e), several comments assert such written procedures are crucial. These comments claim that written procedures promote consistency, clearly lay out expectations for employees, facilitate training, and provide a reference for individuals in performing their job functions. One comment states that written procedures for maintaining, cleaning, and sanitizing equipment are an industry standard.

In response to our request for comment on whether written procedures should be required for complying with the proposed requirements for preparing the master manufacturing record under proposed § 111.45, one comment states that written procedures for in-process control and quality checks should ensure the addition of the proper ingredients in the proper amount, and proper blending and control of other critical points. Another comment states written procedures are a critical element for ensuring consistent implementation of proper corrective action. Other comments state they do not support a requirement for written procedures for preparing the master manufacturing record; and one comment suggests such a written procedure is not necessary because the proposed regulations for preparing the master manufacturing record already delineate the requirements for what information must be included in the master manufacturing record.

In response to our request for comment on whether written procedures should be required for complying with the proposed requirements for laboratory operations under proposed § 111.60, some comments specifically note the need for written procedures for the laboratory test methods used to ensure that components, in-process materials, and finished product meet established specifications. Some comments emphasize written procedures would create a standard for testing of products or groups of products and establishing parameters for passing or failing products.

In response to our request for comment on whether written procedures should be required for complying with the proposed requirements for manufacturing operations under proposed § 111.65, one comment asserts this is an effective way to train personnel and a means to hold operators accountable to a quality standard. Another comment states written procedures can improve quality and consistency in a manufacturing operation.

In response to our request for comment on whether written procedures should be required for complying with the proposed requirements for packaging and labeling operations under proposed § 111.70, one comment asserts this is an effective way to train personnel and a means to hold operators accountable to a quality standard.

Responding to our request for comment on whether written procedures should be required for complying with the proposed requirements for holding components, dietary supplements, packaging, labels, and in-process materials under proposed §§ 111.80 and 111.82, one comment asserts this is an effective way to train personnel and a means to hold operators accountable to a quality standard. Another comment states a company cannot be considered to be a CGMP operation without having written procedures for every product manufacturing activity, including holding and distributing. This comment states mixups and adulterations will be more likely to occur if there are no written procedures for control of storage locations, manner of storage, and container and storage location identification codes.

In response to our request for comment on whether written procedures should be required for complying with the proposed requirements for returned dietary supplements, one comment states written procedures should govern all return and salvage operations to create a standard for quarantine and salvage and to establish parameters for proper salvage conditions.

Responding to our request for comment on whether written procedures should be required for complying with the proposed requirements for handling consumer complaints, some comments state written procedures will encourage companies to handle consumer complaints in a uniform manner. One comment asserts written procedures should be required for handling consumer complaints because some complaints could relate to serious illness or injury. The comment states that written procedures would set out exactly what steps need to be taken when complaints are reviewed, and are the best way to ensure the essential information is captured.

(Response) We agree with the comments that effective process control, using written procedures, is an important aspect of a successful CGMP program. We also agree requiring written procedures will help to ensure consistent practices in operations i.e., help to ensure the operation is conducted in the same manner regardless of who conducts the operation or when the operation is conducted. We also agree that written procedures provide a sound basis for employee training and supervision, are an effective communication tool, and enable quality control personnel to carry out the responsibility to approve or reject all processes, specifications, controls, tests, and examinations, and deviations from or modifications to them. In addition, written procedures establish expectations for each covered operation so the operation does not proceed in an ad-hoc manner. Written procedures provide specific guidance if there is an unanticipated occurrence and, thus, can play a key role in ensuring a quality product, because actions to correct the unanticipated occurrence can take place swiftly and with confidence in the outcome.

This final rule establishes the minimum CGMPs necessary for activities related to manufacturing, packaging, labeling, and holding dietary supplements to ensure a quality

product. The operations required by this final rule must be conducted in a consistent manner, regardless of who is conducting an operation or when the operation is conducted. As discussed in the following paragraphs, with a few exceptions, we are requiring that you establish and follow written procedures to fulfill the requirements for the operations covered by this final rule. The exceptions include final subpart A, which addresses the scope of the rule, rather than operations covered by the rule; final subparts E, H, and I, in which we conclude that a requirement for written procedures would be redundant to other requirements; and final subpart P, which establishes requirements for making and keeping records, rather than for conducting operations.

We believe requiring you to establish and follow written procedures to fulfill the requirements of subparts B through D, F, G, and J through O, when combined with other requirements of this final rule, justifies reduced requirements for testing finished batches of product compared to the proposed requirements for such testing as found in proposed § 111.35. By establishing and following written procedures, you will focus your production and process control system on ensuring the quality of the finished product at each stage in the production process, rather than relying entirely on testing at the end of the process.

2. Written Procedures That Are Required by This Final Rule

a. *Written procedures for personnel (final subpart B).* We believe that successful programs for process control are directly connected to appropriate training programs. Employee training must be conducted in a consistent manner, regardless of who conducts the training or when it is conducted. Failure to conduct employee training in a consistent manner could lead to a failure in ensuring product quality. For example, an employee who has not received appropriate training on how to conduct a specific physical examination to verify the identity of a dietary ingredient may erroneously report that the correct ingredient was received when, in fact, the received dietary ingredient is related to, but different from, the ingredient that is specified in the master manufacturing record.

We also believe the requirements that apply to preventing microbial contamination due to sick or infected personnel and that apply to proper hygienic practices must be conducted in a consistent manner. For example, it is well known that foodborne illness can be transmitted by workers who are sick. For example, volunteer food workers at an outdoor music festival were found to be the source of contamination for an outbreak of *Shigellosis* (Ref. 11).

We include in final subpart B a requirement (final § 111.8) that you establish and follow written procedures for fulfilling the requirements of subpart B.

b. *Written procedures for cleaning the physical plant, including pest control (final subpart C).* We agree with the comments that written procedures for cleaning the physical plant would reduce the potential for cross-contamination and that such written procedures must include written procedures for pest control. Cleaning operations and pest control must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Failure to conduct cleaning operations and pest control in a consistent manner could lead to failure in ensuring product quality. For example, application of a chemical such as a fumigating agent or rodenticide in a production area must be performed correctly to avoid contaminating dietary supplements. Therefore, we disagree that written procedures would not directly prevent contamination or ensure the identity, purity, strength, and composition of the dietary supplement even if a manufacturer maintains the physical plant in a clean and sanitary condition.

We include in final subpart C a requirement that you establish and follow written procedures for cleaning the physical plant and for pest control (final § 111.16).

c. *Written procedures for calibrating instruments and controls and for calibrating, inspecting, and checking automated, mechanical, or electronic equipment (final subpart D).* Calibrating instruments and controls, and calibrating, inspecting, and checking automated, mechanical, or electronic equipment must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Without a consistent approach, the performance of these operations could lead to equipment that produces inaccurate results. For example, if a scale is out of calibration, the wrong amounts of components could be added to a mixer. We include in final subpart D a requirement that you establish and follow written procedures for calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement (final § 111.25(a)) and for calibrating, inspecting, and checking automated, mechanical, and electronic equipment (final § 111.25(b)). We note that the manufacturers of equipment often provide written procedures for calibrating equipment. Depending on your circumstances and applications, you may be able to rely on written procedures provided by the manufacturer of the equipment with little or no modification.

Final § 111.25(a), pertaining to establishing and following written procedures for calibrating instruments and controls used in manufacturing or testing components or dietary supplements, is similar to proposed § 111.25(c)(1) which would provide an option, in relevant part, that you establish written procedures for calibrating such instruments and controls in addition to requiring you to document that the procedure was followed each time a calibration is performed.

d. *Written procedures for maintaining, cleaning, and sanitizing equipment and utensils (final subpart D).* Maintaining, cleaning, and sanitizing equipment and utensils must be conducted in a consistent and appropriate manner, regardless of who conducts the operation or when it is conducted. Failure to clean and sanitize equipment and utensils in a consistent and appropriate manner could lead to a product that is adulterated because, for example, equipment and utensils that are not properly cleaned and sanitized could be a source of microorganisms, or could lead to cross-contamination of products. In addition, failure to maintain equipment in a consistent manner could lead to the failure to ensure product quality. For example, equipment that is properly maintained is less likely to malfunction than equipment that is not maintained, and using equipment that malfunctions could lead to errors in production, such as dispensing an incorrect amount of each ingredient.

We include in final subpart D a requirement that you establish and follow written procedures for maintaining, cleaning, and sanitizing equipment and utensils (final § 111.25(c)). Final § 111.25(c) applies to equipment, utensils, and any other contact surfaces used in labeling operations as well as in manufacturing, packaging, and holding operations. Although the factors you must consider for maintaining, cleaning, and sanitizing equipment used for labeling operations likely are different from those for equipment used in manufacturing or packaging operations, you nevertheless must determine the appropriate steps to take to ensure that labeling equipment is appropriately maintained and does not become a source of contamination

for dietary supplements. For example, equipment used for labeling operations has a greater potential to contaminate a dietary supplement when labeling operations are carried out in concert with packaging operations, because the dietary supplement could be exposed to one or more contact surfaces during the packaging operations.

Final § 111.25(c) requires you to establish and follow written procedures for maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces used to manufacture, package, label, or hold components or dietary supplements. Final § 111.25(c) relates to proposed § 111.25(e)(1) which would, in relevant part, require you to maintain, clean, and sanitize as necessary, all equipment, utensils, and contact surfaces used to manufacture, package, label, or hold components, dietary ingredients, or dietary supplements.

(Comment 8) Some comments suggest that written procedures for maintaining, cleaning, and sanitizing equipment require visual inspection of equipment when more than one product is manufactured using the same equipment, and that the presence of residual components from one product in a different product could be harmful. The comments also suggest the written procedures include residual limits of components from different product lines to guarantee the safety of the dietary supplement.

(Response) The final rule gives you flexibility to develop written procedures appropriate to your products and equipment. Consequently, final § 111.25(c) neither requires nor prohibits any specific procedure, such as the visual inspection suggested by the comment.

As for the residual limits, the comment provides no data or other information that would provide a basis for setting residual limits for any particular components. However, as we discuss more fully in the discussion of final § 111.70(e) in section X of this document, the final rule requires you to establish and meet specifications for the identity, purity, strength, and composition of dietary supplements and for limits on contamination for dietary supplements that you manufacture. When considering the specifications you must establish to ensure the quality of the dietary supplements, you must take into account the need to ensure that components or dietary supplements are not contaminated as a result of using the same equipment. Such equipment could be a source of contamination if more than one product is manufactured using the equipment and it is not properly cleaned and/or sanitized.

e. *Written procedures for quality control operations, including written procedures for conducting a material review and making a disposition decision and written procedures for approving or rejecting reprocessing (final subpart F).* Quality control operations must be conducted in a consistent manner. Failure to carry out quality control operations in a consistent and appropriate way could lead to failure to ensure product quality and to ensure the dietary supplement is packaged and labeled as specified in the master manufacturing record. For example, you could use a component that should not have been released for use in manufacturing, or you could distribute a packaged and labeled dietary supplement that should not have been released for distribution.

We include in final subpart F a requirement that you establish and follow written procedures for quality control operations (final § 111.103). We agree with the comments that there should be written procedures for investigating failures in manufacturing operations. In the 2003 CGMP Proposal, we referred to the process of investigating such failures as a ''material review'' and proposed a series of requirements related to a material review and the disposition decision that follows a material review. The review must be conducted in a consistent manner, and the criteria for making a disposition decision must be consistent, regardless of who is conducting the material review or when it is conducted, and regardless of who makes the disposition decision and when the decision is made. For example, if you do not have written criteria for determining whether a deviation from specifications has resulted in, or could lead to, adulteration, different individuals who conduct a material review could reach different decisions regarding the appropriate disposition of the affected dietary supplement, including decisions that incorrectly result in the release of an adulterated product. As discussed more fully in sections X and XI of this document, the final rule requires that quality control personnel conduct all required material reviews and make all required disposition decisions. Therefore, we are requiring that the written procedures for quality control operations include written procedures for conducting a material review and making a disposition decision (final § 111.103).

We considered the comments that suggest that there should be a requirement for you to establish and follow written procedures for reprocessing from two perspectives: (1) Determining whether reprocessing should be approved or rejected and (2) performing the reprocessing. In general, reprocessing is performed when there is a problem with the manufacturing process, such as when a specification is not met or any step in the master manufacturing record is omitted. Depending on the nature of the dietary supplement, the manufacturing process, and the problem, reprocessing may or may not be able to correct the problem. From the perspective of determining whether reprocessing should be approved or rejected, under the final rule it is quality control personnel who must approve or reject any reprocessing (see final §§ 111.90, 111.113, 111.120, 111.123, and 111.130). The decision to approve reprocessing must be made in a consistent manner, regardless of who conducts the operation or when it is conducted. For example, if it is not possible to test the product at the finished batch stage to determine whether the reprocessing corrected the problem (because, for example, there is no scientifically valid method available to test for a specification that is directly related to the reason for reprocessing), you must have a clear basis to decide that reprocessing will actually correct the problem or you will not know if all required specifications can be met. Without written procedures for approving reprocessing, different individuals who approve or reject any reprocessing could make very different decisions on when reprocessing can correct a problem and when it cannot. Therefore, we are specifically requiring that the written procedures for quality control operations include written procedures for approving or rejecting any reprocessing.

From the perspective of performing the reprocessing, we agree that any procedure for reprocessing must be written because, for example, quality control personnel may need to rely on the procedure that you followed to determine whether all specifications are met for the reprocessed material. However, the final rule requires you to document any reprocessing in the batch record (final § 111.260(n)) rather than establishing and following written procedures to conduct reprocessing, because the actual procedure you follow to reprocess a dietary supplement likely will be different depending on the circumstances.

f. *Written procedures for components, packaging, labels, and product that is received for packaging and labeling as a dietary supplement (final subpart G).* We agree with the comments that the

receipt, examination, quarantine, and release from quarantine of components, packaging, labels, and product that are received for packaging and labeling as dietary supplements must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Failure to carry out these operations in a consistent way could lead to failure to ensure product quality if, for example, you use a component that should not have been released for use in manufacturing.

We include in final subpart G a requirement that you establish and follow written procedures for fulfilling the requirements of subpart G (final § 111.153).

g. *Written procedures for laboratory operations (final subpart J).* Testing and examination of components, packaging, labels, and product that are received for packaging or labeling as a dietary supplement, or packaged and labeled dietary supplements, must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. The reason a firm conducts these tests and examinations is to ensure that a dietary supplement meets established specifications. Failure to conduct tests and examinations in a consistent manner could lead to failure in ensuring the quality of the dietary supplement. For example, a test designed to determine the concentration of a product before it is diluted to the appropriate concentration could provide different results if it is conducted in a different manner by different individuals.

In addition, laboratory operations such as use of criteria for establishing appropriate specifications and use of sampling plans for obtaining representative samples must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. For example, failure to consider that specifications are needed to ensure that a dietary supplement derived from a botanical source does not contain contaminants, such as an unlawful pesticide, could result in a dietary supplement that contains unsafe levels of a contaminant.

We include in final subpart J a requirement that you establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met (final § 111.303).

h. *Written procedures for manufacturing operations (final subpart K).* We agree with the comments that written procedures for manufacturing operations would be an effective way to train personnel, provide a means to hold operators accountable to a quality standard, and improve quality and consistency in a manufacturing operation. The final provisions for manufacturing operations require you to design or select manufacturing processes to ensure that dietary supplement specifications are consistently achieved, conduct all manufacturing operations in accordance with adequate sanitation principles, and take all necessary precautions to prevent contamination of components and dietary supplements. These manufacturing operations must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Failure to perform these operations in a consistent way could lead to failure to ensure the quality of the dietary supplement. For example, surfaces that come in contact with a dietary supplement are potential sources of microbial contamination if consistent procedures are not in place to ensure good sanitary practices. We are including in final subpart K a requirement that you establish and follow written procedures for manufacturing operations (final § 111.353).

i. *Written procedures for packaging and labeling operations (final subpart L).* We agree with the comments that written procedures for packaging and labeling operations are an effective means to hold operators accountable to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. The final provisions for packaging and labeling operations require that you fill, assemble, package, label, and perform other related operations in a way that ensures the quality of the finished product, including practices such as cleaning and sanitizing all filling and packaging equipment, utensils, and containers; protecting manufactured dietary supplements against airborne contamination, using sanitary handling procedures; taking actions to prevent mixups; and suitably disposing of obsolete packaging and labels. These packaging and labeling operations must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Failure to perform these operations in a consistent way could lead to a failure to ensure the quality of the dietary supplement and that the dietary supplement is labeled and packaged as specified in the master manufacturing record. For example, if you do not have procedures for identifying filled, but unlabeled, containers of dietary supplements, mixups could occur before the labels are applied. The final product could contain ingredients other than those identified on the label specified in the master manufacturing record. Therefore, we include in final subpart L a requirement that you establish and follow written procedures for packaging and labeling operations (final § 111.403).

j. *Written procedures for holding and distributing operations (final subpart M).* We agree with the comments that written procedures for holding and distributing operations are an effective means to hold operators accountable to CGMP standards, and that mixups and other problems that affect the final product will be more likely to occur if there are no written procedures for operations such as control of storage locations, manner of storage, and container and storage location identification codes. The final provisions for holding and distributing operations require, among other things, that you hold components and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and dietary supplements are not affected; that you hold components, dietary supplements, and in-process materials under conditions that do not lead to the mixup, contamination, or deterioration of components or dietary supplements; and that you distribute dietary supplements under conditions that will protect them against contamination and deterioration.

These holding and distributing operations must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Failure to follow these requirements for holding and distributing in a consistent manner could lead to a failure to ensure the quality of the dietary supplement product. For example, if employees do not know how to store an in-process batch of a botanical dietary supplement to control humidity, the growth of mold could be promoted. Furthermore, if a distributor does not refrigerate a dietary supplement that requires refrigeration to ensure its strength, the dietary supplement may not meet its specification for strength. Therefore, we include in final subpart M a requirement that you establish and follow written procedures for holding

and distributing operations (final § 111.453).

k. *Written procedures for returned dietary supplements (final subpart N).* We agree with the comments that written procedures for returned dietary supplements would help to ensure appropriate handling of such supplements prior to a disposition decision. The final rule requires you, among other things, to identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision. You must destroy, or otherwise suitably dispose of, any returned dietary supplement that quality control personnel do not approve for salvage or reprocessing. These operations for returned dietary supplements must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Failure to comply with these requirements for quarantine, salvage, and disposition in a consistent way could lead to a failure to ensure the quality of the dietary supplement. For example, if an investigation leads to a conclusion that a dietary supplement requiring refrigeration to ensure its strength was not refrigerated while held at a customer's warehouse, and this dietary supplement was not quarantined while quality control personnel conducted a material review, the dietary supplement could be inadvertently co-mixed with other containers of that same lot of product and then inadvertently redistributed. Therefore, we are including in final subpart N a requirement that you establish and follow written procedures to fulfill the requirements of subpart N (final § 111.503).

l. *Written procedures for product complaints (final subpart O).* We agree with the comments that written procedures for handling consumer complaints (now called product complaints) will encourage companies to handle product complaints in a consistent manner and help ensure the essential information is captured during investigation of a product complaint. The final rule requires you, among other things, to review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications; investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications; and extend the review and investigation of the product complaint to all relevant batches and records. These operations must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. Failure to comply with these requirements for review and investigation of a product complaint in a consistent way could lead to a failure to ensure the quality of the dietary supplement. For example, if you do not have a procedure in place to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications, you may not recognize that a particular product complaint is indicative that a problem has occurred with one of your manufacturing processes. That undiscovered problem may lead to continued distribution of product that is contaminated or otherwise not consistent with your specifications in the master manufacturing record. Therefore, we include in final subpart O a requirement that you establish and follow written procedures to fulfill the requirements of subpart O (final § 111.553).

3. Written Procedures That Are Not Required by This Final Rule

a. *Written procedures for final subpart E (''Requirement to Establish a Production and Process Control System'').* In the CGMP proposal, we did not specifically request comments on whether we should require that you establish and follow written procedures to fulfill the requirements of proposed § 111.35 (''What Production and Process Controls Must You Use?''), and we received no specific comments regarding whether we should establish and follow such written procedures. Given the strong support in the comments for the use of written procedures in a production and process control system, we nonetheless considered whether the requirements that we establish in final subpart E, *Requirement to Establish a Production and Process Control System*, would require written procedures.

Final subpart E requires that you implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary supplements and that your system be designed to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in your master manufacturing record (final §§ 111.55 and 111.60); implement quality control operations to ensure the quality of dietary supplements and that the dietary supplement is packaged and labeled as specified in your master manufacturing record (final § 111.65); establish specifications (final § 111.70); determine whether specifications are met (final §§ 111.73 and 111.75); collect representative samples (final § 111.80); hold reserve samples of packaged and labeled dietary supplements (final § 111.83); have quality control personnel conduct all required material reviews and make all required disposition decisions (final § 111.87); and adhere to certain requirements for treatment, in-process adjustments, and for reprocessing (final § 111.90).

In considering whether we should require that you establish and follow written procedures to fulfill the requirements of final subpart E, we evaluated whether requirements in other subparts that address specific operations for the production and process control system substitute for the requirement of written procedures in final subpart E.

Final subparts F through M establish specific requirements for manufacturing, packaging, labeling, and holding dietary supplements, including requirements for quality control operations (final subpart F); components, packaging, labels, and product that is received for packaging and labeling as a dietary supplement (final subpart G); establishing a written master manufacturing record and batch record (final subparts H and I); laboratory operations (final subpart J); manufacturing operations (final subpart K); packaging and labeling operations (final subpart L); and holding operations (final subpart M). We require you to establish and follow written procedures to fulfill the requirements of final subparts F, G, J, K, L, and M. Given these requirements, we conclude it would be redundant to require you to establish and follow written procedures to fulfill the requirements of final §§ 111.55, 111.60, and 111.65 in subpart E.

Final subpart J requires you to establish and follow laboratory control processes that include the use of criteria for establishing appropriate specifications (final § 111.315(a)); use of sampling plans for obtaining representative samples (final § 111.315(b)); use of criteria for selecting appropriate examination and testing methods (final § 111.315(c)); use of criteria for selecting standard reference materials used in performing tests and examinations (final § 111.315(d)); and use of test methods and examinations in accordance with established criteria (final § 111.315(e)). In addition, under final § 111.303 you must establish and follow written procedures for laboratory operations. Given the requirements of final subpart J, we conclude it would be redundant to require you to establish and follow written procedures to fulfill

the requirements of final §§ 111.70, 111.75, and 111.80 in subpart E.

Final subpart M establishes requirements for holding reserve samples. Under final § 111.453, you must establish and follow written procedures for holding operations. Given the requirements of final subpart M, we conclude that it would be redundant to require you to establish and follow written procedures to fulfill the requirements of final § 111.83 in subpart E for reserve samples.

Final subpart F establishes requirements for quality control personnel to conduct a material review and make a disposition decision (final § 111.113); approve any reprocessing (final § 111.123(a)(5)); and document any material review and disposition (final § 111.140(b)(3)). In addition, as discussed, under final § 111.103 you must establish and follow written procedures for quality control operations. Given the requirements of final subpart F, we conclude that it would be redundant to require that you establish and follow written procedures to fulfill the requirements of final §§ 111.87 and 111.90 in subpart E.

We conclude that it would be redundant to require you to establish and follow written procedures for each of the requirements established in final subpart E. We, therefore, do not require you to establish and follow written procedures to fulfill the requirements established in subpart E.

b. *Written procedures for preparing the master manufacturing record (final subpart H) and for preparing the batch record (final subpart I).* As discussed in the 2003 CGMP Proposal (68 FR 12157 at 12203), a master manufacturing record is analogous to a recipe that sets forth the ingredients to use, the amounts of ingredients to use, the tests to perform, and the instructions for preparing the quantity the recipe calls for. This master manufacturing record helps ensure that you manufacture each ingredient or dietary supplement in a consistent and uniform manner. If you neglect to follow the master manufacturing record, you might not add all of the necessary components in the appropriate strength or amount, and this could result in a final product not consistent with the master manufacturing record. Thus, you must follow a written master manufacturing record in a consistent manner, regardless of who conducts the operation or when it is conducted.

However, we agree with the comments that the specific requirements for what must be in the master manufacturing record make it unnecessary to require written procedures for preparing the master manufacturing record. Under final subpart H, the master manufacturing record must include written instructions, including specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record; procedures for sampling, testing, and examinations; specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record; special notations and precautions to be followed; and corrective action plans for use when a specification is not met. With all of this detail specified for the written instructions the master manufacturing record must include, we believe a written procedure for developing a master manufacturing record can be optional. Therefore, we do not require you to establish and follow written procedures for preparing the master manufacturing record.

A batch is prepared by following the written instructions provided in the master manufacturing record. The master manufacturing record functions as a written procedure for the production of the batch. Therefore, we do not require you to establish and follow written procedures for the batch production record because such practices would be redundant to the requirements for the master manufacturing record in final subpart H.

c. *Written procedures for records and recordkeeping (final subpart P).* Final subpart P establishes general requirements for making and keeping records required in other subparts. We did not request comments on written procedures, nor did we receive any comments that supported such a requirement. Because we believe that requiring written procedures to fulfill subpart P requirements would be redundant or unnecessary, we do not require such written procedures.

d. *Written procedures for product recalls.* We acknowledge that a product recall by persons who manufacture, package, label, or hold dietary supplements must be conducted in a consistent manner, regardless of who conducts the operation or when it is conducted. However, the final rule does not establish any requirements for product recalls. Therefore, we do not require you to establish and follow written procedures for product recalls. However, we encourage you to refer to our ''Guidance for Industry: Product Recalls, Industry Removals and Corrections'' (Ref. 12) (available at *http://www.fda.gov/opacom/7alerts.html*).

D. Other Comments on Written Procedures

(Comment 9) One comment stresses the need for flexibility in requiring written procedures, based on differences between individual activities and companies. The comment suggests companies should be required to review and determine the need for written procedures at each critical step of their operations and be prepared to defend those determinations as necessary.

(Response) To the extent the comment suggests we do not require any written procedures specific to a particular function or requirement, and allow firms to decide when and when not to include them, we disagree. We believe that written procedures for the specific operations we have identified should not be optional. We have no objection if firms decide to establish and follow additional written procedures, beyond those we require in this final rule. Although we require written procedures for entire subparts, or specific requirements within certain subparts, we provide flexibility for firms to establish those written procedures that will ensure the requirements are met.

(Comment 10) Some comments stress the importance of written procedures in enabling FDA to ensure compliance with the dietary supplement CGMP requirements.

(Response) We believe written procedures will help us to ensure compliance with these CGMP requirements because they will clearly communicate the steps the firm must take to satisfy the requirements. During an inspection, we observe the practices that employees follow. However, to ensure that a firm is consistently complying with CGMP requirements, our investigators need access to records that both describe a firm's processes and procedures and demonstrate whether the firm has been following them. Under the final rule, we require you to make and keep records of the written procedures in each applicable subpart. Such records would be available to us under the requirements of final subpart P, *Records and Recordkeeping*.

(Comment 11) Many comments object to FDA's stated reasons for not requiring written procedures for most activities, including concerns about cost control and burden reduction. The comments contend that written procedures

actually save time and other resources because they greatly facilitate employee training and ensure that activities are performed consistently and correctly. Some comments assert most companies already have written procedures in place, so start-up costs associated with such requirements would be minimal. One comment notes written procedures would be among the least costly of all the procedural requirements proposed by FDA.

(Response) We agree that requiring that operations be conducted using written procedures can save time and other resources by facilitating employee training and ensuring operations are performed consistently and correctly. Because following written procedures can help ensure uniformity in the process and ensure the quality of the dietary supplement at every step, periodic end product testing can be sufficient to determine whether your manufacturing process is controlled. CGMP is premised upon quality assurance at every step of the process. It is less costly to establish and follow written procedures than it would be to test each finished batch for conformance with specifications. As suggested by these comments, our analysis (section XXIV of this document) shows that the overall costs are reduced, in part, because requiring that certain operations be conducted using written procedures enables us to reduce requirements for testing at the finished batch stage.

(Comment 12) One comment states training employees on the required hygienic practices prior to their first day of handling product is critical to ensuring product safety.

(Response) The requirement to establish and follow written procedures to fulfill the requirements of subpart B does not establish any fixed requirement for when an employee must receive such training relative to when the employee handles product. However, final § 111.12(c) requires that any person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person's assigned functions. We therefore assume that employees will have the necessary education, training, or experience for each operation that they perform before they perform it.

(Comment 13) Some comments make recommendations for what written procedures should contain, including general parameters that should be included in all written procedures and specific parameters that should be included in specific written procedures. The general parameters include identification of the company; title that reflects the activities to be performed; identification or control number with a revision level code; effective date; the number of pages in the procedure (e.g., by a procedure such as listing page numbers using a convention such as ''page 1 of 4''); approval date and signature(s); references to linked or related procedures or forms; definitions of technical terms and acronyms; list of equipment, materials, and supplies needed in performing the task; who has the responsibility for performing each task; when and where a task is to be performed; concise step-by-step instructions for performing the task; the expected results from performing the task; what data to collect; and how to analyze, file, or report the collected data. In the specific case of written procedures for cleaning equipment and utensils, some comments suggest the written procedures include descriptions of appropriate cleaning agents, methods of cleaning, and the intervals and schedules for cleaning equipment.

(Response) We agree the suggestions provided by these comments are useful to include in any written procedures. However, to provide the flexibility necessary to address diverse dietary supplement manufacturing processes, we are leaving details such as these to the judgment of the company rather than prescribing them within the final rule.

(Comment 14) Some comments request the final rule include requirements for managing changes to written procedures. One comment states changes to written procedures should be reviewed, justified, documented, approved, and implemented in a defined manner. The comments explain that ''Change control procedures'' define what is and what is not covered by the written procedure and how proposed changes will be identified or recommended, processed, reviewed, and approved.

(Response) As discussed in final subpart F, the final rule requires that quality control personnel approve all written procedures. ''All'' written procedures includes revisions to written procedures. As discussed in this section, the final rule requires you to establish and follow written procedures for quality control operations. We believe that procedures for managing changes to written procedures can be addressed within the written procedures for quality control operations.

(Comment 15) Some comments assert the final rule should not require written procedures for key operations because the rule should stay focused on end results and not process.

(Response) We disagree. The essence of good manufacturing practice that is established by this final rule is a production and process control system that is designed to ensure the quality of the dietary supplement.

E. What Other General Comments Did We Receive?

(Comment 16) Some comments say any final rule should not require written procedures, should not propose a definition of appropriate tests, and generally should not include requirements for procedures better left to ''normal business practices.'' The comments cited Executive Order 12866 and the Small Business Regulatory Enforcement Flexibility Act (SBREFA). The comment added that there is no such requirement in the food CGMPs or in the 1997 ANPRM.

(Response) We disagree the final rule violates either Executive Order 12866 or SBREFA and discuss this in section XXIV of this document. We address SBREFA's regulatory flexibility issues by staggering compliance dates so that certain businesses would have 24 and 36 months, respectively, to comply with the final rule. As for the assertion that food CGMPs do not require written procedures, we discuss the requirements of food CGMPS in relation to the requirements of these dietary supplement CGMPs in section V of this document. The comment's assertion that the 1997 ANPRM did not contain written procedures is incorrect. The industry draft that we published in the 1997 ANPRM had multiple written procedures, including written procedures for:

- Cleaning and maintaining equipment and utensils used in the manufacture of products;
- The receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw materials;
- Appropriate tests and/or examinations to be conducted to assure the purity, composition, and quality of the finished product;
- The method for reprocessing batches or operational start-up materials that do not conform to finished goods standards or specifications;
- The control procedures employed for the receipt, storage, handling, sampling, examination, and/or testing that may be necessary to assure the identity of labeling and the appropriate identity, cleanliness, and quality characteristics of packaging materials for dietary products;

• Ensuring correct labels, labeling, and packaging materials are issued and used for dietary products; and

• Describing the handling of all written and oral complaints regarding a product.

(62 FR 5700 at 5704 through 5706).

(Comment 17) In the analysis of impacts in the 2003 CGMP Proposal (68 FR 12157 at 12222), we stated that we had considered imposing fewer CGMP requirements for the manufacture of vitamins and minerals. Although this issue arose as a discussion of regulatory options that we had considered and rejected, we received several comments on this subject. Some comments state we should not create different CGMP standards based upon the type of dietary ingredient. These comments state that one set of appropriately flexible standards would be more efficient and less confusing to industry than separate standards for each portion of the industry. Some comments say that different requirements for vitamins and minerals would cause problems because most people who use these products take a multivitamin/mineral preparation as their primary and sole dietary supplement, so the risk of adverse events arising from adulteration, misidentification, or misformulation of products would be much higher if vitamins and minerals were subject to fewer requirements compared to other dietary supplements. Other comments supported the concept of differing standards. Some comments assert, in order for the CGMP regulations to set minimum quality standards for all dietary supplements, we would have to regulate each facet of the manufacture, packaging, and storage of a dietary supplement independently of product type. These comments state reducing the requirements for vitamin and mineral manufacturers would not allow the development of minimum quality standards across the entire dietary supplement industry.

(Response) The concept of fewer requirements for vitamins and minerals was simply one regulatory option we considered as part of the 2003 CGMP Proposal's analysis of impacts (see 68 FR 12157 at 12220 through 12223). We rejected it (id.). We disagree with the comments that there should be fewer CGMP requirements for vitamins and minerals. Neither the 2003 CGMP Proposal, nor this final rule, imposes fewer requirements on vitamin or mineral firms compared to firms that make other types of dietary supplements.

V. What Legal Authority Comments Did We Receive?

Many comments were submitted from individuals, companies, and trade groups concerning our legal authority for this rule. Most of the comments question the scope of the rule based on the language in section 402(g) of the act (21 U.S.C. 342(g)) stating that ''regulations shall be modeled after current good manufacturing practice regulations for food.'' Other comments question our authority for records access. Some comments assert that certain provisions of the proposed rule are unconstitutionally vague, and therefore violate the Fifth Amendment. A few comments disagree with our rationale for why dietary supplements are different than conventional food and need separate CGMP requirements. We address these comments immediately below in this section.

A. Modeled After CGMP for Food

(Comment 18) Some comments support our approach of proposing requirements that are more comprehensive than the CGMP requirements for food. One comment states that the current requirements for food CGMP are less comprehensive than the CGMP requirements in current use by both the food and dietary supplement industries and the current ''best practices'' should be incorporated into the dietary supplement CGMP rule. Several comments state that the requirements for dietary supplement CGMP do not need to be identical to the requirements in existing food CGMP regulations, that appropriate manufacturing controls are needed for dietary ingredients contained in dietary supplements to protect the public health, that some borrowing of drug CGMP concepts may be necessary, and that we should balance effective control with necessary flexibility in the dietary supplement CGMP rule. In addition, one comment states that the USP manufacturing guidelines, which contain wording from the drug CGMP requirements, are a model for dietary supplement CGMP for many in industry.

Several comments express concern about not deviating too drastically from the requirements in existing food CGMP regulations. Although several comments recognize that additional CGMP provisions for dietary supplements, such as those related to identity, purity, strength, quality, and composition, are needed, the comments say that we should not regulate dietary supplement manufacturing in the same manner as drug manufacturing because it would entail overly burdensome methods for production and process controls. Some comments contend that some of the proposed rule requirements exceed the drug CGMP requirements.

Most of the comments assert that the proposed dietary supplement CGMP requirements are not modeled after the CGMP regulations for food. The reasons for this assertion vary. Some assert that certain provisions in the proposed rule were not found in, or differ from, the provisions in part 110. Examples of proposed requirements that comments indicate exceeded food CGMP included batch testing, packaging and labeling, recordkeeping, consumer complaints, and the use of validated methods. Other comments state that the proposed requirements exceeded those for food because the proposed rule provided for finished testing of certain substances when used as dietary supplements, such as garlic and ginger, whereas no such testing is required under existing food CGMP regulations when those same substances are used as conventional food. One comment says the rule was modeled after juice hazard analysis and critical control point (HACCP) and therefore goes beyond existing food CGMP regulations.

Some comments assert that the proposed requirements exceed the existing food CGMP regulations because certain proposed provisions contained a level of detail that is not in the food or the drug CGMP regulations, or because elements of a provision in the proposed rule were similar to a provision in part 210 (21 CFR part 210) (drug CGMP regulation). Other comments disagree with our rationale that the proposed rule was designed on the same principles as the existing food CGMP regulations to address the characteristics and hazards specific to dietary supplements, or to prevent adulteration in preparing, packaging, or holding dietary supplements. The comments also disagree that we may include provisions in the dietary supplement CGMP final rule that were not found in the food CGMP regulations at the time DSHEA was enacted.

Several comments state that we exceed our legal authority for the proposed rule because it used too broad a definition of ''modeled after.'' Some comments offer their own definitions of ''model;'' others object to the use of the noun form ''model'' and provide dictionary definitions of the verb form ''modeled.'' A few comments assert that the meaning of ''model'' is clear, despite different dictionary meanings, and that the statute is not ambiguous under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council*, 467 U.S.

837 (1984) (''*Chevron*''). One comment states that, even if the language is ambiguous and our interpretation merits deference, our interpretation is too expansive and not based on a permissible construction of the statute. Another comment states that we did not explain why our interpretation was consistent with our congressional mandate.

(Response) We agree with the comments stating that the dietary supplement CGMP requirements in this final rule need not be identical to the existing food CGMP regulations and that a system of manufacturing controls specific to dietary supplements is needed. We do not agree that we exceeded the scope of our authority under section 402(g) of the act in issuing the proposed requirements for dietary supplement CGMP or these final requirements. Our interpretation of the language in section 402(g) of the act, including the ''modeled after'' language, as to what requirements of the act we have authority to issue, is based on a permissible construction of the statute.

The comments present the following general questions: (1) Whether the statute gives us authority to promulgate CGMP requirements for dietary supplements that are not identical to the requirements in existing CGMP regulations for food and (2) if so, whether the requirements in this final rule that differ from those in existing CGMP regulations for food are fairly encompassed within Congress' direction that the dietary supplement regulations shall be ''modeled after'' food regulations and, therefore, are based on a permissible construction of the statute.

Under section 402(g)(1) of the act, a dietary supplement is deemed to be adulterated if it has ''been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).'' Section 402(g)(2) of the act authorizes the Secretary, by regulation, to ''prescribe good manufacturing practices for dietary supplements.'' Congress further provided that such regulations ''shall be modeled after current good manufacturing practice regulations for food'' and ''may not impose standards for which there is no current and generally available analytical methodology.''

In construing the meaning of section 402(g) of the act, and, in particular, the language in that section stating that such regulations shall be ''modeled after current good manufacturing practice regulations for food,'' we are confronted with two questions. First, has Congress directly and unambiguously spoken to the precise question at issue? (''*Chevron* step one'') (see *Chevron*, 467 U.S. at 842.) To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (see *Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, we must implement Congress's unambiguously expressed intent (see *Chevron*, 467 U.S. at 842–843). Second, if the act is silent or ambiguous with respect to a particular issue in section 402(g) of the act, is our interpretation based on a permissible construction of the statute (''*Chevron* step two'') (*Chevron*, 467 U.S. at 843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000))? When Congress leaves a gap for the agency to fill by regulation, the regulation will pass muster so long as it is not ''arbitrary, capricious, or manifestly contrary to the statute'' (*Chevron*, 467 U.S. at 843–844).

We believe that the language in section 402(g) of the act provides an express delegation of authority to us to promulgate a regulation to ''prescribe good manufacturing practices for dietary supplements'' so long as those regulations are ''modeled after the current good manufacturing practice regulations for food.'' The express language in section 402(g) of the act contemplates broad, but not unlimited, agency discretion as to what to include in a dietary supplement CGMP regulation.

Congress has also spoken to the precise question of whether the dietary supplement CGMP requirements must be identical to the requirements in existing food CGMP regulations. If Congress had wanted dietary supplement CGMP to be identical to food CGMP, it easily could have required that by statute. Indeed, if Congress had intended for CGMPs for dietary supplements to be the same as food CGMPs, there would have been no need for Congress to have addressed the issue at all; as a type of food, dietary supplements would otherwise be governed by the food CGMPs. See section (ff) of the act (21 U.S.C. 321(ff)). Instead, the statute calls for us to issue regulations that are ''modeled after'' CGMP regulations for food. The plain meaning of a ''model'' or ''modeled after,'' as discussed in the 2003 CGMP Proposal (68 FR 12157 at 12165) and in the comments, relates to a pattern, plan, representation, or simulation. The use of the term ''modeled after'' makes it clear that the regulations need not be identical to the original, but instead are contemplated to differ from the original.

Thus, the additional, independent authority to promulgate CGMP regulations for dietary supplements that Congress provided in section 402(g) of the act, without delineating what requirements such a regulation could or could not include, left us with considerable authority to fill in the gaps in ways that recognize the differences between dietary supplements and other foods that warrant different manufacturing controls. A contrary interpretation, as some comments suggested, that the ''modeled after'' language means the requirements for dietary supplement CGMP must be precisely found in current part 110, or other food CGMP regulations, would so narrowly circumscribe our discretion as to make it impossible to tailor the regulation to fit the products it is designed to address. Such an interpretation would lead to a rule that would ''frustrate the success of the regulation undertaken by Congress'' because it would not take into consideration the characteristics, hazards, and manufacturing practices specific to dietary supplements (*American Trucking Ass'ns* v. *U.S.*, 344 U.S. 298, 311 (1953)).[4]

Congress has also spoken to the precise question of which requirements CGMP ''regulations for food.'' The plain meaning of ''*regulations*'' is plural (more than one), and the plain meaning of ''food'' is as Congress defined in section 201(f) of the act, including articles ''used for food or drink.'' At the time DSHEA was enacted, there were five food CGMP regulations: Those for infant formula (part 106), thermally processed low-acid canned food (part 113), acidified food (part 114), bottled water (part 129), and general food (part 110, often referred to as the ''umbrella'' regulations). All of these regulations appear in Subchapter B of Chapter 1 of Title 21 of the Code of Federal Regulations, entitled ''Food for Human Consumption.'' Nothing in the language of section 402(g) or elsewhere suggests that Congress meant to limit the term CGMP ''regulations for food'' to only the regulation in part 110. Thus, it is

[4]The Senate Report on DSHEA states that Congress inserted section 402(g) because it recognized that ''dietary supplements may require different manufacturing and quality controls'' when compared to food CGMP (S. Rep. No. 140, 103rd Cong., 2d Sess., at 31 (1994)). However, the report is not considered legislative history. Congress issued a Statement of Agreement (140 Cong. Rec. S14801 (Oct. 7, 1994), reprinted in 1994 U.S.C.C.A.N. 3523) that stated ''it is the intent of the chief sponsors of the bill * * * that no other reports or statements be considered as legislative history for the bill'').

consistent with our statutory authority for us to look to all of our food CGMP regulations—including infant formula, low-acid canned foods, acidified foods, and bottled water, as well as our general food CGMP regulations—after which to model our dietary supplement CGMP regulations.

Congress has not spoken to the precise question of what specific requirements for dietary supplements may be imposed under the ''shall be modeled after'' language. Given this ambiguity, therefore, under *Chevron* step two, we may determine what requirements to include in this final rule for dietary supplement CGMP, provided that our interpretation is not arbitrary, capricious, or manifestly contrary to the statute (*Chevron*, 467 U.S. at 844).

Accordingly, we considered the types of requirements in the existing food CGMP regulations and used those as models for the dietary supplement CGMP requirements. We considered both the objectives and the means of achieving the objectives in the existing food CGMP regulations. These CGMP food regulations include those for infant formula (part 106), general food (''umbrella'' regulations) (part 110), thermally processed low-acid canned food (part 113), acidified food (part 114), and bottled water (part 129). Each of these food CGMP regulations provides objectives and means upon which we modeled the dietary supplement CGMP regulations. Just as the precise requirements of the other food CGMP regulations are tailored to the particular characteristics and hazards of the foods and manufacturing processes being addressed, the dietary supplement CGMP requirements are also so tailored.

For example, the infant formula CGMP regulation is intended to ensure that the ''safety and nutritional potency'' of a formula are ''built into the manufacturing process'' in order to establish a quality control system to make sure that infant formula products are properly manufactured (47 FR 17016 at 17017, April 20, 1982). The specific criteria in the regulations apply in determining whether the infant formula meets the safety, quality, and nutrient requirements of the act (§ 106.1(a)). The means to achieving the objectives in the infant formula regulations include, for example, requirements for ingredient control (through a supplier's guarantee or certification or through analysis of the ingredient) (§ 106.20); preparation of a master manufacturing order and a system to assure and verify the addition of each ingredient (§ 106.25); either in-process batch testing (§ 106.25(b)) or sampling and testing of each batch to ensure nutrient requirements are met (§ 106.30); and coding to enable ready identification of lots during their sale and distribution (§ 106.90).

The infant formula CGMP regulation also includes numerous requirements that manufacturers maintain records, e.g., records on certain food-packaging materials; records on nutrient premix testing; certificate and guarantees from premix suppliers for required nutrients; records of results of testing conducted by suppliers; records of tests to establish the purity of each nutrient, the weight, and amounts of nutrients; records to ensure proper nutrient quality control; records to ensure required nutrient control at the final product stage; distribution records; records on microbiological quality and purity of raw materials; and records of audits (§ 106.100). The infant formula CGMP regulation also requires manufacturers to maintain procedures describing how complaints will be handled, to follow those procedures, and to investigate when a complaint shows a possible health hazard (§ 106.100(k)). Quality control records must contain enough information to permit a public health evaluation of any batch of infant formula (§ 106.100(o)). All required records must be available for authorized inspection (§ 106.100(l)).

Many provisions of the dietary supplement CGMP final rule are similar in objective and means and are ''modeled after'' the provisions of the infant formula CGMP regulation. For example, like the infant formula regulation, the dietary supplement CGMP regulation is designed to establish a quality control system to make sure that dietary supplements are properly manufactured. The dietary supplement regulation uses similar means to ensure this goal, such as requirements for ingredient control (through supplier's certificate of analysis or testing or examination) (final § 111.75(a)); preparation of a master manufacturing record (final § 111.205); in-process batch monitoring (final § 111.75(b)) or batch testing or examination (final § 111.75(c)); and coding to provide a batch, lot, or control number (final § 111.260(a)). Like the infant formula CGMP regulations, the dietary supplement CGMP final rule contains recordkeeping requirements related to packaging materials; certificates of analysis from suppliers; results of tests that you conduct, for example, on ingredients or the finished batch; and results of chemical, microbiological, or other tests that you conduct as necessary to prevent the use of contaminated components (final §§ 111.95, 111.180(b)(2), 111.260(h), 111.325(b)(2), and 111.365(d)). Also similar to the infant formula CGMP regulation, the dietary supplement CGMP final rule requires manufacturers to maintain procedures for handling complaints (final §§ 111.553 and 111.570(b)(1)); to investigate certain complaints (final § 111.560(a)(2)); and to keep records of complaints (final § 111.570(b)(2)). Required dietary supplement records must also, as with infant formula records, be available for inspection by FDA (final § 111.610(a)).

The ''umbrella'' food CGMP regulation in part 110 details practices to ensure ''(1) that food is manufactured, processed, packed, and held under conditions that are sanitary, and (2) that such food is safe, clean, and wholesome'' (44 FR 33238 at 33239, June 8, 1979). Promulgated primarily under the adulteration provisions of section 402(a)(3) and (a)(4) of the act, as well as section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), the umbrella CGMP food regulation requires a quality control operation whose main purpose is ''to provide a systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act'' (51 FR 22458 at 22461, June 19, 1986), as well as to prevent the spread of food-borne communicable diseases (44 FR 33239, June 8, 1979) (see § 110.5(a)). Part 110 also ''specifies requirements that must be met to produce safe and wholesome food'' (51 FR 22461). These umbrella food CGMP requirements not only pertain to food safety, but also are ''concerned with contamination by filth or decomposition which may or may not raise safety concerns'' (51 FR 22458 at 22462).

The detailed requirements of the umbrella food CGMP regulation accomplish these objectives through a variety of means. For example, there are specific personnel provisions requiring employees who may be sources of microbial contamination to be excluded from certain operations (§ 110.10(a)); persons working in contact with food, food-contact surfaces, and food-packaging materials to follow hygienic practices (§ 110.10(b)); and that certain personnel have sufficient education or experience to produce clean and safe food (§ 110.10(c)). The umbrella food CGMP regulation also includes detailed requirements concerning the grounds surrounding a food plant and the design of buildings and structures to protect against contamination or to maintain sanitary operations and produce safe food (§ 110.20). Detailed provisions also require that physical facilities be

maintained in sanitary condition and in sufficient repair to prevent food from being adulterated (§ 110.35). Any water that contacts food or food-contact surfaces must be ''safe and of adequate sanitary quality'' (§ 110.37(a)); plumbing, sewage, and other disposal, as well as toilet facilities, must also protect against contamination (§ 110.37(b), (c), and (d)). Similarly, equipment and utensils must be designed and maintained to preclude adulteration and food contact surfaces must be maintained to protect food from being contaminated by any source, including unlawful indirect food additives (§ 110.40(a)). All operations for receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing food must be conducted using adequate sanitation principles (§ 110.80). Appropriate quality control operations must be used to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable (§ 110.80). Foods must be stored and transported under conditions to protect against physical, chemical, and microbial contamination, as well as against deterioration of the food and the container (§ 110.93).

The provisions of the umbrella food CGMP regulation serve as the model for many dietary supplement CGMP provisions. For example, the dietary supplement CGMP requirements concerning personnel and microbial contamination (final § 111.10(a)); hygienic practices (final § 111.10(b)); and education, training, or experience (final § 111.12) are very similar to provisions in part 110. In addition, the dietary supplement CGMP requirements concerning the grounds, physical plant facilities, cleaning materials, pest control, water supply, plumbing, sewage disposal, bathrooms, and trash disposal (final §§ 111.15 and 111.20) closely resemble the analogous part 110 requirements.

Because of the particular hazards associated with low-acid canned foods and with acidified foods, the CGMP regulations for these foods contain detailed provisions to ensure safe manufacturing. Specifically, the CGMP regulations for these foods protect the public health against microbial contamination from these foods. Part 113 sets out safe manufacturing, processing, and packaging procedures for low-acid foods in hermetically sealed containers. The CGMP criteria in this part apply in determining whether the facilities, methods, practices, and controls used by commercial processors of such foods are operated ''in a manner adequate to protect the public health'' (§ 113.5). Processors of low-acid canned foods must have a ''scheduled process'' that is established by a qualified person and is ''adequate under the conditions of manufacture for a given product to achieve commercial sterility'' (§§ 113.3 and 113.83). ''Commercial sterility'' of thermally processed food means a condition achieved by applying heat to render the food free of certain microorganisms (§ 113.3). Part 113 requires that supervisors satisfactorily complete training at a school approved by FDA (§ 113.10).

Part 113 also contains extremely detailed requirements on equipment and procedures. For example, each vessel used for pressure processing in steam must be equipped with a mercury thermometer that is tested for accuracy at least once a year, or more frequently if necessary, to ensure its accuracy (§ 113.40(a)(1)). Critical factors (variation of which may affect the attainment of commercial sterility) must be specified in the scheduled process and must be measured and recorded on processing records frequently enough to ensure that the factors are within the specified limits (at least every 15 minutes) (§§ 113.40(a)(13) and 113.83). Observations and measurements of certain operating conditions must be made and recorded at intervals of sufficient frequency to ensure that commercial sterility of the food product is being achieved (at least every hour) (§ 113.40(g)(2)(ii)(c)). There must also be a system to stop packaging operations (or to segregate products) when the packaging conditions fall below scheduled processes (§ 113.40(g)(2)(ii)(b)). Regular observations of container closures are required to be made and recorded (§ 113.60). Each container must be coded ''to enable ready identification of lots during their sale and distribution'' (§ 113.60(c)).

Before using raw materials and ingredients susceptible to microbiological contamination, the low-acid food processor must ensure that they are ''suitable for use in processing low-acid food'' (§ 113.81(a)). Complete records covering all aspects of the establishment of the scheduled process and of certain confirmation tests must be maintained permanently (§ 113.83). Scheduled processes must be readily available to any duly authorized FDA employee (§ 113.87(a)). Whenever any process is less than the scheduled process or when critical factors are not in control, the low-acid food must be reprocessed or set aside for further evaluation as to public health significance (§ 113.89). Unless the evaluation demonstrates that the product is free of microorganisms of potential public health significance, the product either must be reprocessed to render it commercially sterile or destroyed (§ 113.89).

All process deviations involving a failure to satisfy the minimum requirements of the scheduled process must be recorded and kept in a separate file detailing the deviations and actions taken (§ 113.89). Detailed information on processing and production must be entered on forms (§ 113.100(a)). Not later than 1 working day after the actual process, and before the food is shipped or released for distribution, a qualified representative of management must review all processing and production records for completeness and to ensure that the product was subjected to the scheduled process (§ 113.100(b)). Records to identify the initial distribution of the finished product must be kept to facilitate segregation of lots that may have become contaminated or otherwise rendered unfit for their intended use (§ 113.100(d)). Records must be maintained at the processing plant for at least 1 year after the date of manufacturing and at a reasonably accessible location for another 2 years (§ 113.100(e)).

Similarly, the CGMP regulation for acidified food in part 114 requires supervision by personnel trained at an FDA-approved school (§ 114.10); manufacturing in accordance with a scheduled process established by a qualified person (§§ 114.80 and 114.83); processing sufficient to destroy the vegetative cells of certain microorganisms (§ 114.80(a)(1)); sufficient control, including frequent testing and recording of results, to ensure that the finished hydrogen-ion concentration (pH) values are not higher than 4.6 (§ 114.80(a)(2)); testing and examinations of containers to ensure that the food is suitably protected from leakage or contamination (§ 114.80(a)(4)); and coding to enable ready identification of lots during their sale and distribution (§ 114.80(b)).

Whenever any acidified food process operation deviates from the scheduled process or the pH of the finished product exceeds 4.6, the processor must reprocess it, process it under part 113 requirements, or set it aside for evaluation as to any potential public health significance (§ 114.89). Unless the evaluation demonstrates that the food has undergone a process that has rendered it safe, the food must be fully reprocessed to render it safe or be destroyed (§ 114.89).

A record must be made of the procedures used in the public health

evaluation and the results of the evaluation (§ 114.89). Records must be kept of examinations of raw materials, packaging materials, and finished products, and of suppliers' guarantees or certifications that verify compliance with our regulations (§ 114.100(a)). Processing and production records showing adherence to scheduled processes must be maintained and must have sufficient additional information such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion (§ 114.100(b)). Departures from scheduled processes having a possible bearing on public health or the safety of the food must be recorded and kept in a separate file or log, along with the action taken to rectify the departure and the product disposition (§ 114.100(c)). Records must be kept identifying initial distribution of the finished product to facilitate segregation of lots that may have become contaminated or otherwise unfit for their intended use. Copies of certain required records must be kept at a reasonably accessible location for 3 years from the date of manufacture (§ 114.100). The criteria in the part 114 regulation, as well as those in part 110, apply in determining whether an article of acidified food is adulterated under section 402(a)(3) of the act in that it has been manufactured under such conditions that it is unfit for food or under section 402(a)(4) of the act in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (§ 114.5).

Many provisions of parts 113 and 114 also serve as models for provisions in the dietary supplement final rule. In many instances, the analogous provision in the dietary supplement final rule allows more flexibility in the means to achieve the goal. For example, under final § 111.13 qualified personnel must be assigned to supervise the manufacturing, packaging, labeling, or holding of dietary supplements. Although the supervisor must be qualified by education, training, or experience to supervise, the more restrictive requirement of parts 113 and 114 to attend an FDA-approved school is not included. The ''scheduled process'' for low-acid and acidified food manufacturing, processing, and packing is analogous to the required ''system of production and process controls'' that dietary supplement manufacturers must design and implement (final §§ 111.55 and 111.60(a)). Similarly, the ''critical factors'' required to be specified in the scheduled process for low-acid and acidified foods are akin to the ''specifications'' that dietary supplement manufacturers must establish for certain points in the manufacturing process (final § 111.70). Just as low-acid food processors must establish procedures to ensure that ingredients are suitable for use, so too must dietary supplement manufacturers establish component and finished product specifications (final § 111.70(b) and (e)). Just as containers for acidified food must ensure suitable protection from contamination, packaging that comes into contact with dietary supplements must be safe and suitable for use (final § 111.70(d)). Dietary supplement in-process points, like the ''critical factors'' for low-acid and acidified food, must be monitored to detect any deviation or unanticipated occurrence that may result in adulteration (final § 111.75(b)(2)).

Rejected dietary supplements must also be held under quarantine (final §§ 111.370 and 111.425); dietary supplements which have been reprocessed, treated, or which have had in-process adjustments must meet all established product specifications and be approved before release (final § 111.90(c)). Similar to coding low-acid or acidified foods, dietary supplements must have assigned batch, lot, or control numbers (final § 111.415(f)). The design, calibrations, and cleaning of equipment and utensils must also result in the equipment and utensils being suitable for their intended uses and not result in contamination of components or dietary supplements (final § 111.27). Written procedures for the various controls are required (see, e.g., final §§ 111.8, 111.25, and 111.103), and required written records (see, e.g., final §§ 111.14, 111.23, 111.35, and 111.95) must be kept for 1 year past the shelf life date, if shelf life dating is used, or 2 years after the date of distribution of the last associated batch of dietary supplement (final § 111.605). All required dietary supplement CGMP records must be readily available for inspection and copying by FDA (final § 111.610(a)).

Finally, the bottled water CGMP regulation was promulgated to ensure the safety and sanitary quality of these products, which include all water processed and bottled for human consumption (38 FR 32563, November 26, 1973). The criteria in part 129, as well as in part 110, apply in determining whether the facilities, methods, practices, and controls used to process, bottle, hold, and ship bottled drinking water conform with good manufacturing practice ''to assure that bottled drinking water is safe and that it has been processed, bottled, held, and transported under sanitary conditions'' (§ 129.1). Part 129 requires plant construction and design features, such as a separate bottling room and an enclosed room for washing and sanitizing containers, to protect against contamination (§ 129.20). All plant equipment and utensils must be suitable for their intended use (§ 129.40(a)).

Both the product water supply and the operations water supply must be of a ''safe, sanitary quality'' in conformance with ''the applicable laws and regulations of the government agency or agencies having jurisdiction'' (§ 129.35(a)). Samples of source water must be analyzed at least once a year for chemical contaminants and once every 4 years for radiological contaminants (§ 129.35(a)(3)). Source water from other than a public water system must be sampled and analyzed for microbiological contaminants at least once a week (id.). The product water-contact surfaces of all containers and equipment must be clean and adequately sanitized and protected from contamination (§ 129.37(a) and (b)). Filling, capping, closing, sealing, and packaging of containers must be done so as to preclude contamination of the water (§ 129.37(d)). All product water contact surfaces must be nontoxic and in compliance with section 409 of the act (21 U.S.C. 348) (concerning food additives) (§ 129.40(a)(2)).

Numerous production processes and controls for bottled water are also required. For example, all treatment of product water must be effective in accomplishing its intended purpose and in accordance with section 409 of the act (§ 129.80(a)). The treatment processes must be performed with equipment and substances that will not adulterate the product (§ 129.80). Product water samples must be taken before bottling and analyzed as often as necessary to assure uniformity and effectiveness of the processes performed by the plant (§ 129.80(a)). Cleaning and sanitizing solutions must be sampled and tested to assure adequate performance (§ 129.80(c)).

Each unit package from a batch or segment of continuous production run must be identified by a production code (§ 129.80(e)). The plant must maintain information on the kind of product, volume, date, lot code, and distribution of finished product to wholesale and retail outlets (id.). During the process of filling, capping, or sealing the containers, performance must be monitored and the filled containers inspected to assure that they are sound, properly capped or sealed, and coded

and labeled (§ 129.80(f)). All containers and closures must be sampled and inspected to ascertain that they are free from contamination (id.).

To assure that the plant's production of bottled water complies with applicable standards, laws, and regulations, the plant must analyze product samples at specified intervals (§ 129.80(g)). The methods used to analyze the samples must be approved by the government agency with jurisdiction (§ 129.80(g)(3)). Records of the date of sampling, type of product sampled, production code, and results of analysis must be maintained (§ 129.80(g)(3)). All required records must be maintained at the plant for at least 2 years (§ 129.80(h)) and be available for official review by FDA at reasonable times (id.).

Provisions of the bottled water CGMP regulation also serve as a model for provisions of the dietary supplement CGMP regulation. For example, water that is used in a manner such that the water may become a component of a dietary supplement must at a minimum comply with applicable Federal, State, and local requirements and not contaminate the dietary supplements (final §§ 111.15(e)(2) and 111.365(c)). Precautions that must be taken to prevent contamination of components or dietary supplements include performing chemical, microbiological, or other testing (final § 111.365(d)). Filling, assembling, packaging, labeling, and related operations must be performed to protect the dietary supplement against adulteration (final § 111.415). Equipment and utensils must be suitable for their intended use (final § 111.27(a)). Safe and adequate cleaning compounds and sanitizing agents must be used (final § 111.15(c)(1)). Representative samples of each batch must be examined to ensure that the product meets established specifications (final § 111.415(g)). Each lot of packaged and labeled dietary supplement must be assigned a batch, lot, or control number (final § 111.415(f)).

Moreover, our interpretation of permissible requirements for the dietary supplement CGMP regulation is also consistent with the use of the terms ''good manufacturing practice'' and ''current good manufacturing practice'' in section 402(g) of the act. Although these terms are not defined in the act, GMP is generally used to refer to methods used in, and the facilities and controls used for, product manufacturing and related activities.[5] The umbrella food CGMP regulation, for example, defines the ''plant'' covered by the requirements of that regulation as the facility used for, or in connection with, ''the manufacturing, packaging, labeling, or holding of human food'' (§ 110.3(k)). As we have described in detail, the objectives of the existing food CGMP regulations and the precise means (or requirements) used to achieve the objectives vary depending on the particular hazards and characteristics of the products and their manufacturing. For example, the umbrella food CGMP regulation is specifically designed to ensure that food is manufactured, processed, packed, and held under sanitary conditions and that the food is safe, clean, and wholesome. Low-acid and acidified food CGMP requirements focus on facilities, methods, practices, and controls to protect the public health against the particular risks of microbial contamination from these foods. The infant formula CGMP regulation is aimed at ensuring both the safety and nutritional potency of these special foods. Infant formula is often the sole item in the diet. An infant formula that does not meet the requirements for nutritional potency may cause a hazard to the health of the infant (see 61 FR 36154, July 9, 1996). The bottled water CGMP regulation embodies requirements for facilities, methods, practices, and controls used in processing, bottling, holding, and shipping of bottled water to ensure its safety and sanitary quality.

Like the food CGMP regulations after which they are modeled, the dietary supplement CGMP final rule contains criteria for facilities, methods, practices, and controls used in manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Quality includes consistently meeting the established specifications for identity, purity, strength, and composition of the dietary supplement and limits on contaminants, in addition to manufacturing the dietary supplement under conditions to prevent adulteration. As Congress recognized in DSHEA, identity, purity, strength, and composition are essential characteristics for dietary supplements (see, e.g., section 403(s)(2) of the act (a dietary supplement is misbranded if its labeling fails to list the name and quantity of each dietary ingredient and if it fails to have the identity and strength or the quality, purity, or compositional specifications it is represented to meet)). Yet without information about the identity, purity, strength, or composition, the manufacturer could not know the final contents of the dietary supplements it manufactures or whether its processes are reliably and consistently producing the correct combination and amounts of ingredients in a dietary supplement. Accordingly, the final rule requires a manufacturer to establish specifications for the identity, purity, strength, and composition and for limits on contaminants of the dietary supplements it manufactures and ensure that such specifications are consistently met in the finished batch of dietary supplement (§ 111.75(e)). Dietary supplements, like infant formula, are relied upon by consumers not only to be safe, but also in many instances to provide specific and important claimed health benefits (see, e.g., section 403(r) of the act). In the preamble to the 2003 CGMP Proposal, we discussed a number of examples illustrating adulteration and improper formulation of dietary supplements caused by manufacturing, packaging, or holding practices (68 FR 12157 at 12162 and 12163). These dietary supplement CGMP requirements will help to protect consumers against similar types of adulteration and against reliance on products that are not properly formulated.

Generally recognized principles underlying CGMP also support our interpretation of section 402(g) of the act. Our interpretation of permissible CGMP regulations is reasonable based on recognized principles for controlling the quality of manufactured products in general (Ref. 9). As many comments asserted, if the dietary supplement CGMP requirements are to be meaningful, they must ensure quality in the finished product (see, for example, the discussion in section X of this document of comments regarding the production and process control system). Controls to ensure quality include planning processes to determine desired product features or characteristics, a system of controls to ensure that the desired product will be consistently produced, and making necessary improvements to the process (section 2.6 of Ref. 9). Manufacturers must plan what they intend to produce, institute adequate controls to achieve the desired outcome, and ensure that the controls

[5] Although the act does not define ''current good manufacturing practice,'' the term is used elsewhere in the statute (see, e.g., sections 501(a)(2)(B) (drug CGMP) and 520(f)(1)(A) of the act (device CGMP) (21 U.S.C. 351(a)(2)(B) and 21 U.S.C. 360j(f)(1)(A), respectively). Case law supports the agency's view that ''current'' does not mean ''actually prevailing manufacturing practice'' in an industry and that such a practice need not be accepted by a majority of manufacturers (*National Ass'n of Pharmaceutical Mfr's* v. *Department of Health and Human Services*, 586 F. Supp. 740, 752 (S.D.N.Y. 1984)). Nevertheless, the requirements of this final rule embody current practices of many food and dietary supplement manufacturers, as reflected in the comments supporting the provisions of the proposed rule.

work so that the desired outcome is consistently achieved. If the outcome is not consistently achieved, corrective actions need to be implemented in order to reach the desired outcome.

This final rule, like the other food CGMP regulations, embodies the basic concepts of controlling quality, i.e., planning, control, and improvement. As discussed earlier in the ''Overview of CGMP'' (section III.A of this document), we have defined the term ''quality'' for this dietary supplement CGMP regulation to mean ''that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the Federal Food, Drug, and Cosmetic Act.'' Identifying the desired characteristics of identity, purity, strength, and composition of a dietary supplement, as required in this final rule, is an essential part of the planning process to manufacture a dietary supplement. Without identifying specifications for each of these characteristics of a dietary supplement, it is not possible to control for, and repeatedly and reliably produce, the desired end product. Similarly, requirements for batch testing ensure that there is consistency from batch to batch. Packaging and labeling requirements ensure that suitable packaging is used and that the label identified in the master manufacturing record for the product is placed on the finished product. In addition, requirements related to consumer complaints help to ensure that manufacturers are made aware of problems related to their manufacturing processes, including those that may result in illness or injury, so that they can take corrective actions to prevent any future problems from occurring. The procedures for production and process control in this final rule also include as key elements measures to prevent contamination that could adulterate the product. Requirements to protect against contamination during the manufacturing, packaging, labeling, and holding operations help ensure that this aspect of ''quality'' is also achieved for dietary supplements. In sum, this final rule embodies principles for controlling quality through requirements designed to ensure both that the dietary supplement meets its established specifications for identity, purity, strength, and composition and that it is not adulterated.

The dietary supplement CGMP requirements are also reasonable because they take into consideration the different product forms in which these products will be manufactured. Unlike conventional foods, such as fruit, vegetables, cereals, and dairy products, dietary supplements will be sold in tablet, capsule, powder, or softgel form. They may also be sold as a concentrate, metabolite, constituent, or extract of a vitamin, mineral, herb, botanical, or dietary substance. Because dietary supplements are often sold in different forms than conventional foods, different processes and controls are needed to manufacture dietary supplements than to manufacture conventional foods. For example, equipment must be able to manufacture dietary supplements in tablet or softgel form. Therefore, the final rule requires that controls be established to ensure that the equipment functions in accordance with its intended use (final § 111.30(e)) and will consistently manufacture a product in whatever form is desired. Consistent with basic CGMP principles, ensuring the quality of the dietary supplement product requires that the manufacturer establish precisely what it will produce (specifications for its product), how it will make the product (processes), and which process controls and tests it will use to ensure reliable, reproducible results. These CGMP requirements will help to achieve these results.

The dietary supplement CGMP requirements are also reasonable when viewed in the context of the act as a whole. *See Brown & Williamson*, 529 U.S. at 133. Our mission is, in part, to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled (section 903(b)(2)(A) of the act) (21 U.S.C. 393(b)(2)(A))). Section 701(a) of the act (21 U.S.C 371(a)) gives us the authority to promulgate regulations for the efficient enforcement of the act in order to ''effectuate a congressional objective expressed elsewhere in the Act'' (*Association of American, Physicians and Surgeons, Inc.* v. *FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass'n.* v. *FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980)). The final rule is designed to help ensure that dietary supplements consistently are manufactured to produce the product established by the manufacturer, to bear the label identified in the master manufacturing record, and to prevent adulteration. The requirements are written to facilitate efficient and effective action to enforce their terms when necessary.

Some provisions of the dietary supplement CGMP final rule may be similar to the existing drug CGMP regulations. However, we have not modeled these regulations after the drug CGMP regulations. Controls that relate to certain product forms (e.g., tablets, capsules, powder, softgel) are required in this final rule based on the specific characteristics of dietary supplements and the hazards associated with these forms, not, as some comments imply, based on a desire to emulate drug CGMP requirements. The act does not state that there may not be similarities between the dietary supplement CGMP requirements and the CGMP requirements for drugs or other non-food products. Inasmuch as food CGMP regulations and other CGMP regulations are all based on CGMP principles, it is neither surprising nor impermissible that there are similarities between the dietary supplement CGMP requirements and drug or device CGMP requirements. Although we do not agree that any of the CGMP requirements exceed drug GCMP requirements, even if a particular requirement did, it is not prohibited under the statute. As long as the CGMP final rule is ''modeled after'' the food CGMP regulations, we have satisfied the statutory requirements. As noted, our interpretation of ''modeled after'' means that the dietary supplement CGMP final rule provisions share similar objectives and/or use similar means as the existing food CGMP regulations. To the extent that there are similarities to drug CGMP regulations, those similarities are appropriate and not prohibited by section 402(g) of the act.

Consistent with our role ''to fill in, through interpretation, matters of detail related to [the statute's] administration,'' *Barnhart* v. *Walton*, 535 U.S. 212, 225 (2002), we applied our scientific expertise, policy judgment, and experience to promulgate dietary supplement CGMP requirements that will protect the public health and effectively implement our statutory authority to prescribe dietary supplement CGMP. See *United States* v. *Mead*, 533 U.S. 218, 227–228 (2001); *Nationsbank of North Carolina* v. *Variable Annuity Life Ins. Co.*, 513 U.S. 251, 256–58 (1995); *Chevron*, 467 U.S. at 844; *Forester* v. *Consumer Product Safety Com.*, 559 F.2d 774, 783 (D.C. Cir. 1977).

B. Records Authority

(Comment 19) Some comments state that requirements related to record keeping and access to such records are necessary to allow our inspectors to assess the adequacy of a dietary supplement manufacturer's practices. Additional comments state that access to records is necessary to ensure that CGMP requirements are followed and to protect the public health. Several comments identify specific types of

records we should require in a final rule, including written procedures, batch and master manufacturing records, distribution records, and lot numbers. Another comment states that training records should be required because the qualifications and training of employees affects product quality.

Other comments, however, state that the record retention and access requirements seem to be modeled after drug CGMP and not food CGMP. Other comments state that, even though records may be necessary to ensure that CGMP requirements are followed, we do not have authority to require access to and copying of such records. Some comments assert the authority to establish regulations for dietary supplement CGMP does not imply there is authority to inspect records. Several comments state we cannot rely on section 701 of the act because there is not another section of the act that authorizes us access to company records for dietary supplement CGMP and section 701(a) of the act does not itself give us the authority we need to require records inspection. Another comment suggests that the absence of an express grant of records inspection authority means that records inspection is not necessary for the efficient enforcement of the act.

Some comments assert that we have no record inspection authority under section 704(a) of the act (21 U.S.C 374(a)). A few comments suggest that, because records inspection authority was not expressly granted in DSHEA's statutory language, as it was for OTC drugs and medical devices, Congress provided no authority for records inspection for dietary supplement CGMP. The comments state that we have a longstanding interpretation that section 704 of the act does not give us access to a food manufacturer's records. Several comments state that it was sufficient to have voluntary records access, stating that many companies are willing to provide access to records.

Other comments say that our record inspection authority for dietary supplement CGMP is limited to that under section 306(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (21 U.S.C. 350(c)), i.e., when we have a ''reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences * * *'' Another comment suggests an alternative standard to that in section 306(a) of the Bioterrorism Act of a ''reasonable belief that there is a public health hazard'' for when we may access records.

One comment cites *In the Matter of Establishment Inspection of Medtronic, Inc.*, 500 F. Supp 536 (D. Minn. 1980), to support its assertion that we exceeded our statutory inspection authority in the dietary supplement CGMP record requirements. One comment states that a warrantless inspection of dietary supplement CGMP records and criminal consequences that may be imposed under the act for failure to comply with the act provide a ''powerful argument against expanding the Agency's inspection authority any further'' and raise ''serious constitutional concerns.'' Several comments ask us to clarify our jurisdiction for records inspection requirements or delete proposed § 111.125(c).

Still other comments seek confirmation that the confidential and trade secret information obtained by us under the rule would be protected from disclosure under applicable statutes. Among other things, the comments cite the Trade Secrets Act, 18 U.S.C. 1905, and the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4). Some comments express concern that records inspection would violate ''rights to privacy of corporate manpower'' or would compromise trade secrets. The comments request the rule specifically reconfirm our obligations under these laws.

(Response) We disagree with the comments suggesting that we have no authority to require dietary supplement manufacturers to maintain records to comply with CGMP under section 402(g) of the act; that the absence of an express grant of records authority means records are not needed for the efficient enforcement of the act; and that Congress meant, by its silence, that we have no authority to issue records requirements. Clearly, just as Congress is not expected to express ''every single evil sought to be corrected'' in a grant of authority to promulgate a rule, it can not be expected to articulate every requirement that is within an agency's delegated authority (*American Trucking Assoc.* v. *United States*, 344 U.S. 298, 309–10 (1953)).

Agencies are expected to bring their expertise to bear on what requirements are necessary that will not ''directly frustrate the success of the regulation undertaken by Congress'' (id. at 311). In this instance, Congress has not expressed any specific intent regarding recordkeeping for dietary supplements but has directed FDA to use other food CGMP regulations, which require recordkeeping and FDA access to records, as models for these regulations. Congress has delegated substantial and sufficiently specific authority to us to promulgate recordkeeping and access regulations (*Cf. United States* v. *Storer Broadcasting*, 351 U.S. 192, 202–03 (1956) (upholding a rule that established limitations on broadcast licensing that were ''not specifically authorized by statute'')). As stated earlier in this section, the ''modeled after'' language in section 402(g) of the act is ambiguous with respect to what specific CGMP requirements we are to include in this final rule. At the time Congress enacted section 402(g) of the act there were several food regulations that contained recordkeeping and record access requirements. We included records requirements in the food CGMP regulations for infant formula (part 106), low acid food (part 113), acidified food (part 114), and bottled water (part 129). Accordingly, the directive in section 402(g) of the act is sufficient authority for our recordkeeping requirements in this final rule. In addition, our authority to establish records requirements has been upheld under other provisions of the act, which lacked explicit recordkeeping authority for FDA, where we have found records to be necessary (*National Confectioners Assoc.* v. *Califano*, 569 F.2d 690, 693–94 (D.C. Cir. 1978) (upholding requirements for source coding and distribution records based on the statutory scheme as a whole)).

Moreover, records are an indispensable component of CGMP. The records required by this final rule provide the foundation for the planning, control, and improvement processes that constitute a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records will show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to control the identity, purity, strength, and composition and limits on contaminants and to prevent adulteration were effective. Further, records will show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. Written procedures also will help ensure that personnel follow hygienic practices; permit evaluation of whether equipment, including software that may run the equipment, performs as it is intended; and help ensure that the

equipment is properly maintained and adequately cleaned.

The CGMP final rule establishes the parameters for the production and process control system in which dietary supplements are to be manufactured. The dietary supplement manufacturer establishes the identity, strength, purity, and composition of the supplement it manufactures (final § 111.70); determines whether the established specifications are met (final § 111,73); uses the tests it needs to ensure that those characteristics are consistently met (final §§ 111.75 and 111.315); and identifies the steps necessary to ensure that any necessary tests or examinations are completed, reviewed, and recorded in a timely fashion before the dietary supplement is released for distribution to the public (final §§ 111.110 and 111.325(b)(2)). The CGMP final rule also requires that the manufacturer establish written procedures for its quality control operations to ensure the personnel performing this function provide proper review and oversight of the production and process control system, have the knowledge and experience to identify and anticipate possible problems in the manufacturing of the dietary supplement, and ensure corrective measures are taken promptly when problems occur (final §§ 111.103 through 111.140). The final rule also requires that the manufacturer establish the ''master recipe(s)'' for the dietary supplement(s) it manufactures so that such recipe(s) can be followed for each batch produced (final §§ 111.205 through 111.210). In sum, manufacturers cannot operate without records because critical elements in a manufacturing process are entirely dependent on information written or captured in the form of a record.[6] Such records are also necessary to protect consumers by enabling manufacturers to identify and recall problematic products as necessary and make necessary corrections to deviations in their processes.

The authority granted us under sections 402(g) and 701(a) of the act not only includes the authority to establish record requirements, but also includes access to such records. Without such authority, the dietary supplement CGMP requirements are, practically speaking, not enforceable. Under section 402(g)(1) of the act, the failure to meet any CGMP requirements, including the failure to have a record that is required by this final rule, renders a dietary supplement so manufactured to be adulterated as a matter of law. The introduction or delivery for introduction into interstate commerce of an adulterated dietary supplement is a prohibited act under section 301(a) of the act (21 U.S.C. 331(a)), and acts done to an ingredient in a dietary supplement, or to a dietary supplement, while held for sale after shipment in interstate commerce that result in the ingredient or dietary supplement being adulterated violates section 301(k) of the act (21 U.S.C. 331(k)). Thus, in order for us to determine whether the dietary supplement product is adulterated and whether a manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring to be kept under section 402(g) of the act.

In light of the foregoing, without access to such records, we would not know whether a manufacturer was complying with the procedures and processes required in this final rule. For example, our investigator must have access to the test results for the identity of a dietary ingredient to determine whether such ingredient meets the manufacturer's specification for identity. The investigator needs to understand, by reviewing a record, what the software that runs a production operation is set up to do and whether it performs those functions to achieve the desired product characteristics. Observation of these processes alone, by an investigator, would not allow that investigator to evaluate compliance with this final rule. Moreover, records often cannot be thoroughly evaluated by the investigator on site. In such cases, records must be readily available to food experts at the Center for Food Safety and Applied Nutrition (CFSAN) and agency consultants. We must have accurate, reliable, and objective data about the manufacturing specifications to be able to achieve an enforceable rule.

We also disagree with comments stating our records inspection authority is limited to that provided by section 306(a) of the Bioterrorism Act. There is no basis to conclude that Congress intended to limit our authority to inspect records, to enforce section 402(g) of the act, to the records inspection authority under the Bioterrorism Act. The Bioterrorism Act, enacted almost 8 years after section 402(g), to address credible threats of serious adverse health consequences or death to humans and animals, required recordkeeping to identify the immediate previous sources and the immediate subsequent recipients of food (21 U.S.C. 350c).

There is nothing in the Bioterrorism Act that reflects any Congressional intent to modify section 402(g) of the act. In fact, section 414(d)(1) of the act (21 U.S.C. 350c(d)(1)), added by section 306(a) of the Bioterrorism Act, shows a contrary intent. Section 414(d)(1) provides that ''This section shall not be construed—(1) to limit the authority of the Secretary to inspect records or to require establishment and maintenance of records under any other provision of this Act.'' Moreover, Congress, in the legislative history to the Bioterrorism Act, supported our general approach of requiring recordkeeping pursuant to authority in section 701(a) of the act in combination with other provisions.[7] We are not relying on section 704 of the act for its underlying authority to require recordkeeping and records access in this final rule. Those comments asserting that we do not have such authority and the underlying references, for example, to past hearings on records inspection authority under section 704 of the act, are not controlling with regard to the action we are taking under sections 402(g) and 701(a) of the act. When there are other bases for jurisdiction and tools to protect the public interest, we may use what ''will be the most effective in advancing the Congressional objective'' (*U.S.* v. *Midwest Video Corp.*, 406 U.S. 649, 656 (1972)).

Some comments stated that our access to dietary supplement records is not consistent with constitutional jurisprudence. We disagree. The comment which expressed concern about ''constitutional issues'' in the context of an FDA inspection of records during a warrantless FDA inspection expressed concern about the criminal liability that could be imposed on a manufacturer under the act (citing *United States* v. *Dotterweich*, 320 U.S. 277 (1944) and *United States* v. *Park*, 421 U.S. 658 (1975)). To the extent that the comment asserts that the records access established in this final rule constitutes an improper search and seizure under the Fourth Amendment, we disagree.

The dietary supplement industry, as the food industry as a whole, is a

[6] It is also worth noting that standard references used in many industries establish clear expectations for documentation and recordkeeping practices for assuring quality control in manufacturing operations (Refs. 9 and 13).

[7] In discussing section 306 of the Bioterrorism Act (Maintenance and Inspection of Records for Foods), Congress stated, ''The managers did not adopt a Senate proposal to authorize the Secretary to require the maintenance and retention of other records for inspection relating to food safety, because the Secretary has authority under section 701(a) of the [act] to issue regulations for the 'efficient enforcement of this Act' and this authority, in combination with other provisions (such as section 402 [of the act]), gives the Secretary the authority to require appropriate record keeping in food safety regulations.'' (H.R. Conf. Rep. No. 107–481, at 135 (2002), (Ref. 14)).

pervasively regulated industry that is subject to warrantless inspections (*see, e.g., United States* v. *Biswell*, 406 U.S. 311, 315 (1972) (''In the context of a regulatory inspection system of business premises * * * the legality of the search depends not on consent but on the authority of a valid statute.''); *United States* v. *New England Grocers Supply Co.*, 488 F. Supp. 230, 238 (D. Mass. 1980) (holding that a warrantless inspection under 21 U.S.C. 374 is ''fully consistent with the Fourth Amendment''); *United States* v. *Acri Wholesale Grocery Co.*, 409 F. Supp. 529, 533 (S.D. Iowa 1976) (holding that a warrantless inspection, which includes photographic activities, conducted under 21 U.S.C. 374 does not violate the Fourth Amendment); *United States* v. *Business Builders, Inc.*, 354 F. Supp. 141, 143 (N.D. Okla. 1973) (''the statute takes the place of a valid search warrant''); *United States* v. *Del Campo Baking Mfg. Co.*, 345 F. Supp. 1371 (D. Del 1972) (finding warrantless inspection of food establishment lawful under 21 U.S.C. 374)).

As explained earlier in this section, we have ample authority, under sections 402(g) and 701(a) of the act, to require that certain records be kept and accessible to us upon inspection. Records access is imperative to the efficient enforcement of the dietary supplement CGMP final rule, and we are not prohibited from requiring access to these records under sections 402(g) and 701(a) of the act (See *Permian Basin Area Rate Cases*, 390 U.S. 747, 780 (1968) (''in the absence of compelling evidence that such was Congress' intention * * * [the court should not] prohibit administrative action imperative for the achievement of an agency's ultimate purposes.'')).

We also disagree with the comment suggesting that voluntary records access is sufficient. In our experience, many manufacturers are not willing, as the comments suggest, to provide records voluntarily to us (Ref. 15). Moreover, it is often the case that the most uncooperative manufacturers are the very ones whose records and processes are deficient. Without mandatory requirements for agency access to records required by the final rule, we could not enforce and there would be minimal incentives for manufacturers to comply with the rule, which would frustrate Congressional intent in enacting section 402(g) of the act.

We also disagree with the comment that cited *In the Matter of Establishment Inspection of Medtronic, Inc.*, 500 F. Supp. 536 (D. Minn. 1980), to suggest that our proposed recordkeeping requirements exceed our statutory inspection authority. As already discussed, we are not relying on section 704 of the act for our authority to require access to dietary supplement CGMP records. Thus, to the extent the comment cited to *Medtronic* as an example of the statutory authority for inspection of device records under section 704 of the act, *Medtronic* is not pertinent to our authority for records access in this final rule.

Finally, we disagree that the records access in this final rule will violate any protection a manufacturer has with respect to protection of confidential commercial or financial information or trade secrets. Trade secrets and commercial or financial information that is privileged or confidential are protected from disclosure under FOIA and other laws (see, e.g., 21 U.S.C. 331(j), 18 U.S.C. 1905). Further, our FOIA regulations set forth the specific procedures for assuring such protection.

It was not clear from the comments what was meant by ''rights to privacy of corporate manpower.'' We note that §§ 20.63 and 20.64 contain provisions for the protection of personal privacy.

C. Public Health Service Act Authority

(Comment 20) One comment acknowledges that we have authority under the PHS Act to regulate intrastate activities that may cause the spread of communicable diseases. The comment states that, in any situation in which we need to exercise our authority over any disease-causing substance within the State where a component or dietary supplement is manufactured, packed, or held, we can and should exercise our authority under the PHS Act. However, the comment asserts that nothing in the preamble clearly states whether we believe that the final rule will be, in its entirety, binding on manufacturers, packers, and holders of dietary supplements who are engaged solely in intrastate commerce, and that we have not requested comment on this specific issue. The comment requests that we clearly state that the final rule applies only to interstate commerce, except for activities that may spread communicable diseases.

(Response) We address each of these issues in turn.

1. The Communicable Disease Risk Posed by Dietary Supplements

There are communicable disease risks related to the manufacture of dietary supplements that are appropriately addressed not only under the act, but, as the comment acknowledges, also under the PHS Act. Microorganisms, including *Salmonella enterica* (Salmonella), *Campylobacter jejuni*, and enterohemorrhagic *Escherichia coli* 0157:H7 (EHEC), are well-known causes of communicable diseases, and may be present in dietary supplements and their components. There are a number of microorganisms that cause communicable diseases and that may be found in components or dietary supplements. These microorganisms cause serious effects and symptoms. For example, Salmonella causes salmonellosis, which affects the gastrointestinal (GI) tract and is characterized by diarrhea, fever, abdominal cramps, headache, nausea, and vomiting (Ref. 16). In a small portion of healthy people (1 to 4 percent), infection spreads from the GI tract into the blood stream, which can be life-threatening. Persons with immune compromising conditions (such as cancer, Acquired Immunodeficiency Syndrome (AIDS), autoimmune disorders) are at greater risk of blood stream infection (Ref. 16).

Campylobacteriosis, often due to infection with *Campylobacter jejuni*, is characterized by diarrhea, fever, and abdominal cramps, which can be severe (Ref. 17). These symptoms frequently relapse, and the disease may become chronic in immune compromised persons. People with campylobacteriosis are also at increased risk of developing certain post-infectious complications, which will prolong their recovery.

EHEC may cause infections with a very low infectious dose (as low as 2 to 45 organisms), and may result in non-bloody and bloody diarrhea, hemolytic-uremic syndrome (a cause of red blood cell destruction, damage of blood vessel walls, and, in severe cases, kidney failure (especially in young children)), thrombotic thrombocytopenic purpura (i.e., a blood disorder characterized by low platelets, low red blood cell count, abnormalities in kidney function, and neurological abnormalities (especially in adults)), and death (Ref. 18).

Animal tissues (e.g., organs from livestock), as well as botanicals, used as components in dietary supplements may contain EHEC, Salmonella, and *Campylobacter jejuni*. In addition, because the same microorganisms are also present in the environment, they may contaminate components during manufacturing activities. Moreover, people who harbor those pathogens could transmit them to components and dietary supplements during processing. Therefore, components and dietary supplements, as potential sources of communicable diseases, may be regulated under the PHS Act.

For these microorganisms (e.g., EHEC, Salmonella, and *Campylobacter jejuni*)

humans carry and transmit infections through their feces or by direct contact with other persons. For other microorganisms, domestic and wild animals serve as the reservoir, and humans become infected when contaminated tissues of infected animals are used in dietary supplements. For both categories of microorganisms, dietary supplements can also become contaminated indirectly by human and animal fecal contamination of water or through the production or processing environment.

Dietary supplements may contain a variety of components derived from domestic and wild animals, such as powders prepared from whole or partial gecko, deer antler velvet, and organs, such as cow liver and brain, pork stomach, or sheep spleen from common domestic livestock. Each of these tissues may be contaminated with microorganisms such as Salmonella, *Campylobacter jejuni*, and EHEC. Even clinically normal animals obtained from safe sources may harbor these communicable pathogens and result in contaminated products (Ref. 19). (Information on these animals and potential pathogens can be accessed at *http://www.fsis.usda.gov/Science/Microbiology/index.asp*). Dietary supplements also may contain crustacean or molluscan shellfish or components prepared from them, such as glucosamine from shrimp exoskeletons and oyster extract, that may be contaminated with *Vibrio* species, including *V. parahaemolyticus*. *Vibrio* species are natural inhabitants of shellfish harvest waters, and shellfish are commonly naturally contaminated, especially during times of the year when harvest waters are warm (Refs. 20 through 23). *V. parahaemolyticus* most often causes gastroenteritis characterized by diarrhea, abdominal cramps, nausea, vomiting, and fever (Ref. 24).

Dietary supplements may also contain botanicals (plants) that may harbor microorganisms, including organisms from animal feces (Salmonella and *Shigella* spp., *Escherichia coli*), and organisms arising from handling (*Staphylococcus aureus*), harvesting, processing, and transportation.

Components contaminated with microorganisms must be treated to prevent the finished dietary supplements from being contaminated. The processes used to manufacture dietary supplements do not, by themselves, always eliminate the microorganisms. Studies show, for example, that microorganisms, such as EHEC and Salmonella, can even survive the tablet production process and thereby expose consumers (Ref. 25).

The industry is aware of the dangers of using components contaminated with Salmonella and other microorganisms. For example, in 2001, a component manufacturer recalled 2,400 pounds of pepsin contaminated with Salmonella. As a result, a number of dietary supplement manufacturers issued recalls for their dietary supplements that contained the pepsin. In the press releases accompanying the recalls, the dietary supplement manufacturers warned consumers of the possible dangers of Salmonella contamination, and encouraged consumers to either destroy or return the supplements (Ref. 26).

Therefore, because of the communicable disease concerns associated with dietary supplements, we are asserting legal authority under the PHS Act in support of the final rule. As discussed in the following section of this document, our authority under the PHS Act is not limited to interstate activities. It also covers intrastate activities.

2. Activities For Which We Are Asserting Legal Authority Under the PHS Act

There are many opportunities for components and dietary supplements to become contaminated with microorganisms that spread communicable diseases. The final rule requires firms to take all the necessary precautions during the manufacture of a dietary supplement to prevent such contamination.

These precautions, for example, include: Performing manufacturing operations under conditions and controls that protect against potential microorganism growth; washing or cleaning components that contain soil or other contaminants; performing microbiological testing, as necessary, to prevent the use of contaminated components; sterilization, pasteurization, freezing, refrigeration, and controlling pH, humidity, and water activity (a_w), or using other effective means to remove, destroy, or prevent the growth of microorganisms and decomposition; and holding components and dietary supplements that can support the growth of infectious microorganisms of public health significance in a manner that prevents them from becoming adulterated.

Failure to properly clean components, or take any other appropriate steps, such as those listed in the previous paragraph, could lead to pathogen growth and the spread of communicable diseases. If, for example, a dietary supplement manufacturer purchased an animal-derived ingredient that harbored *Salmonella enterica*, but failed to take the steps necessary to inactivate the pathogen, the consumption of the dietary supplement could lead to the spread of salmonellosis.

The final rule also requires firms to take measures to exclude from certain operations any sick persons who might contaminate material, including components, dietary supplements, and contact surfaces used to manufacture, package, label, or hold a dietary supplement.

D. The Interstate Commerce Nexus for the Final Rule

1. The PHS Act

(Comment 21) Several comments assert that, although the PHS Act may extend to some intrastate activities, its reach is very limited. The comments appear to conclude that the reach of the PHS Act and the act extends only to situations in which the finished dietary supplement is shipped in interstate commerce.

(Response) We do not agree that this view is correct. The PHS Act extends to intrastate commerce. Under section 361 of the PHS Act (42 U.S.C. 264), we may ''make and enforce such regulations as in [our] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.''

In *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977), the court upheld FDA's regulation that banned the sale of small turtles to prevent the spread of disease caused by turtles harboring Salmonella and *Arizona* microorganisms. The ban covered both interstate and intrastate sales. The court held that the intrastate ban is not only authorized by the law, but, under modern conditions of transportation and commerce ''is clearly reasonable to prevent the interstate spread of disease'' (id.).

We are authorized under the PHS Act to regulate conduct that occurs within a State to the extent necessary to prevent the interstate spread of communicable diseases. Such is the present case with respect to the provisions of the dietary supplement CGMP final rule for which section 361 of the PHS Act provides authority.

2. The Act

The act extends to the sale of a dietary supplement that was manufactured and

distributed entirely in one State, if the supplement contains any ingredient or uses any component that came from outside of that State. Such a dietary supplement is subject to section 301(k) of the act, which prohibits ''[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, *or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded*.'' (emphasis added). *See also* 21 U.S.C. 321(b)(3) (defining food to include articles used as components of food).

The interstate commerce prerequisite under section 301(k) or section 304(a) (21 U.S.C. 334(a)) of the act is established when one or more components used in the manufacture of the product have crossed State lines. This principle is known as ''component jurisdiction'' (*See*, *e.g.*, *Baker* v. *United States*, 932 F.2d 813, 814–15 (9th Cir. 1991); *United States* v. *Article of Food * * * Coco Rico, Inc.*, 752 F.2d 11, 14 (1st Cir. 1985); *United States* v. *Dianovin Pharmaceuticals, Inc.*, 475 F.2d 100, 103 (1st Cir.), cert. denied, 414 U.S. 830 (1973) (''appellants' use of components shipped in interstate commerce to make vitamin K for injection brought their activities within § 331(k)''); *United States* v. *Cassaro, Inc.*, 443 F.2d 153, 155–56 (1st Cir. 1971); *United States*v. *Detroit Vital Foods, Inc.*, 330 F.2d 78, 81–82 (6th Cir.), cert. denied, 379 U.S. 832 (1964); *United States* v. *Allbrook Freezing & Cold Storage, Inc.*, 194 F.2d 937, 939 (5th Cir. 1952); *United States* v. *Varela-Cruz*, 66 F.Supp.2d 274, 277–281 (D. P.R. 1999)).

Nor does it matter that the interstate product component comprises only a minute part of the article, *United States* v. *Miami Serpentarium Laboratories*, [1981—1982 Transfer Binder] Food Drug Cosm. L.Rep. (CCH) paragraph 38,164 at 38,930 (S.D. Fla. 1982); *United States* v. *14 Cases * * * Naremco*, 374 F.Supp. 922, 925 (W.D. Mo. 1974), or if the interstate ingredient combines with others to form a different product. *Detroit Vital Foods*, 330 F.2d at 81; *United States* v. *40 Cases * * * Pinocchio Brand * * * Oil*, 289 F.2d 343, 346 (2d Cir.), *cert. denied*, 368 U.S. 831 (1961).

Finally, we note that section 709 of the act creates a presumption of interstate commerce (see 21 U.S.C. 379a (''In any action to enforce the requirements of this Act respecting a device, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.'')).

In conclusion, the final rule covers not only finished products that have moved in interstate commerce but also products made from ingredients or components that have moved in interstate commerce. This is true regardless of the amount of the ingredient or component in the product and regardless of whether the finished dietary supplement has itself moved in interstate commerce. The final rule also covers products, components, and ingredients that may contribute to the spread of communicable disease, regardless of whether the component, ingredient, or product has itself moved in interstate commerce.

3. Commerce Clause

(Comment 22) One comment states that we must be ''mindful of the limits'' imposed on the regulation of intrastate commerce by the Supreme Court in *United States* v. *Lopez*, 514 U.S. 549 (1995). The comment asserts that we may only regulate intrastate activity that has a ''substantial effect'' on interstate commerce and activity that ''exerts a substantial economic effect on interstate commerce.''

(Response) The final rule is consistent with the *Lopez* decision. Among the cases cited by the Court in *Lopez* as support for its decision is *Wickard* v. *Filburn*, 317 U.S. 111 (1942), which involved the production and consumption of homegrown wheat. In that case, the Court explained: ''although Filburn's own contribution to the demand for wheat may have been trivial by itself, that was not enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial'' (*Lopez*, 514 U.S. at 556). The same is true for dietary supplement manufacturers. Therefore, the requirements of the final rule are consistent with the Commerce Clause of the Constitution.

E. Fifth Amendment

(Comment 23) Several comments allege a number of the sections of the proposed regulation are unconstitutionally vague and violate the Administrative Procedure Act (APA) because the rule would be ''contrary to constitutional right, power, privilege, or immunity.'' The comments express concern that if such terms are not defined or deleted, there would be no fair notice on what conduct is prohibited and would result in ''unbridled discretion'' in how the rule will be enforced. The comments focus on provisions containing words such as ''adequate,'' ''qualified,'' ''readily accessible,'' ''convenient,'' ''suitable,'' ''appropriate,'' and ''necessary.'' For example, one comment notes that proposed § 111.15(e) would require physical plant plumbing to be of an adequate size and design and to be adequately installed and maintained. The comment objects to the section on the ground that ''what constitutes 'adequate' in those contexts is left undefined.''

(Response) We disagree these terms are vague or that the identified terms should be deleted from the final rule. The qualifying terms objected to in the comments have been in use since the umbrella food CGMP rule (part 110) was first promulgated in 1969. For example, this regulation included requirements that: ''[p]lant buildings and structures shall be suitable in size;'' there must be ''sufficient space'' for equipment and storage materials; there must be ''adequate lighting;'' and protection against pests must be provided ''where necessary'' (see 34 FR 6977 at 6978, April 26, 1969). The court in *National Association of Pharmaceutical Manufacturers.* v. *Department of Health & Human Services*, 586 F.Supp. 704 (S.D.N.Y 1986), addressed the very question of whether terms such as ''adequate,'' ''appropriate,'' ''proper,'' ''sufficient,'' and ''suitable,'' in the drug CGMP regulation were vague. The court found that the drug CGMP regulation containing such terms was ''sufficiently definite to give notice of the required conduct to one who would avoid [their] penalties, and to guide the judge in [their] application * * *'' (Id. at 753). The court so held, in part, in light of the fact that the drug CGMP statute was upheld against a constitutional vagueness attack in *United States* v. *Bel-Mar Laboratories, Inc.*, 284 F. Supp. 875, 883 (E.D.N.Y. 1968) (''the phrase 'current good manufacturing practice' is not strange to those in the trade to whom the subject section is directed.''). Furthermore, the use of such ''ordinary terms to express ideas which find adequate interpretation in common usage and understanding'' are not the types of terms that have been held to be unconstitutionally vague (*Boyce Motor Lines* v. *United States*, 342 U.S. 337, 342 (1952)). Some of these very terms have been in use for over 30 years in food CGMP regulations.

No comments were submitted objecting to the use of such terms, when the umbrella food CGMP rule was revised in 1986 (see 51 FR 22458, June 19, 1986). Also, when we began work on the dietary supplement CGMP rule, we

received and published for comment an industry draft of a CGMP regulation for dietary supplements. The industry draft used many of the same terms. For example, it provides in part: ''Plumbing shall be of adequate size and design and adequately installed and maintained'' (62 FR 5700 at 5703, February 6, 1997). Thus, there has been sufficient common usage of these terms in the food industry and, in particular, the dietary supplement industry to enable manufacturers, and those who enforce the requirements, to comprehend and apply such terms ''with a reasonable degree of certainty'' to their particular operations (*Boyce Motor Lines* v. *United States*, 342 U.S. at 340 (''[F]ew words possess the precision of mathematical symbols, most statutes must deal with untold and unforeseen variations in factual situations, and the practical necessities of discharging the business of government inevitably limit the specificity with which legislators can spell out prohibitions [and therefore] no more than a reasonable degree of certainty can be demanded.'')). The same reasoning applies here. It addresses ''untold and unforeseen variations in factual situations'' and, as such, ''no more than a reasonable degree of certainty can be demanded.''

Agencies are permitted to, and indeed must, use such qualifying terms to address the variety of conditions that exist at different companies. We do not need to, nor could we, predict with mathematical precision how many inches or feet, for example, would be ''adequate space'' to allow for cleaning a particular piece of equipment that could be applied to every size of facility and every operation (id.). Moreover, defining such terms too precisely would unduly restrict the application of the regulation to a very narrow, limited set of circumstances and not provide industry with the needed flexibility to address the number and variety of types of manufacturing operations that Congress intended for this rule to cover (see *Freeman United Coal Mining Company* v. *Federal Mine Safety and Health Review Commission*, 108 F.3d 358, 363 (D.C. Cir. 1997) (citations omitted) (upholding a regulation that required equipment to be ''maintained in good repair,'' the court rejected the vagueness challenge: ''specific regulations cannot begin to cover all of the infinite variety of [conditions at firms and that] * * * [b]y requiring regulations to be too specific [courts] would be opening up large loopholes allowing conduct which should be regulated to escape regulation.''); *United States* v. *Bel-Mar Laboratories, Inc.*, 284 F. Supp. at 883 (rejecting a vagueness challenge to the CGMP requirements for drugs, noting that ''[a]s a matter of fact, there are responsible segments of opinion within the industry itself which oppose a greater degree of specificity in this area.'').

Finally, it is important to understand that rules are not unconstitutionally vague simply because they require interpretation by regulated persons. For example, courts have held that the term ''insanitary conditions'' in the act is not unconstitutionally vague (See *Golden Grain Macaroni Co.* v. *United States*, 209 F.2d 166, 168 (9th Cir. 1953) (citing *Boyce Motor Lines*, supra); *Berger* v. *United States*, 200 F.2d 818 (8th Cir. 1952)). In *Berger*, the court rejected the claim that the term ''insanitary condition'' is unconstitutionally vague on the ground that it does not specify the ''degree of insanitation'' required for a violation (id. at 822). A law may require a person to make ''estimates of the degree of dirtiness and lack of sanitation'' which may result in a violation (*id., see alsoBoyce Motor Lines* v. *United States*, 342 U.S. at 340 (It is not ''unfair to require that one who deliberately goes close to an area of proscribed conduct shall take the risk that he may cross the line'')). There are sufficient protections under the act to overcome any concerns related to how it will be criminally enforced. We disagree that such terms will lead to ''unbridled discretion'' on how the rule is enforced.

In short, we find that the rule is not unconstitutionally vague, and does not violate section 706(2)(B) of the APA (5 U.S.C. 706(2)(B)).

F. Miscellaneous

(Comment 24) One comment states that the proposed rule violates section 402(f)(1)(A)(i) and (f)(1)(A)(ii) of the act (21 U.S.C. 342 (f)(1)(A)(i) and (f)(1)(A)(ii)), which deems a dietary supplement adulterated if it contains a dietary ingredient that presents an unreasonable risk of illness or injury under conditions of use in labeling or ordinary conditions of use, if none are suggested or recommended in labeling. Under section 402(f) of the act, the Government bears the burden of proof to show that a dietary supplement is adulterated. The comment states that the proposed rule reversed the presumption under section 402(f) of the act, and would revise the rule to require us to first show a violation under section 402(f) of the act before we could take any enforcement action under section 402(g). Another comment states that, because the rule was intended to enable manufacturers to be able to detect and avoid adulteration through CGMP, the proposed rule created a presumption that dietary supplements are adulterated until proven otherwise.

(Response) The final rule does not violate section 402(f) of the act. Section 402(f) and (g) of the act provide two independent bases under which we may take enforcement action against dietary supplements. A dietary supplement may be adulterated either because a manufacturer has failed to follow a CGMP requirement, or because a dietary supplement presents an unreasonable risk of illness or injury, or both. There would be no reason to assert a second basis for adulteration under section 402(g) of the act if one always had to demonstrate adulteration under section 402(f) of the act as a prerequisite.

We also disagree with the comment that the proposed rule creates a presumption that the dietary supplement is adulterated simply because the proposed requirements would enable a manufacturer to detect and avoid adulteration. The requirements for CGMP are prophylactic and are designed in part to ensure that all aspects of manufacturing, from receipt through distribution, provide the necessary controls and monitoring to ensure the quality of the dietary supplement, including that it is manufactured, packaged, labeled, and held in a manner to prevent adulteration.

(Comment 25) One comment states that, if there is reduced competition through the enforcement of the rule, there will be a secondary effect of elimination of speech on dietary supplement innovative uses.

(Response) The comment seems to conclude that, if a dietary supplement manufacturer is not able to stay in business due to adverse enforcement actions against it by us, or elects to not go into business based on the possibility of enforcement action by us, there will be reduced competition due to fewer products, less labeling, and ''elimination of speech on innovative uses.'' To the extent that the comment is suggesting that the dietary supplement CGMP requirements are unconstitutionally overbroad, this argument is wholly without merit (*Cf. Wisconsin* v. *Mitchell*, 508 U.S. 476, 488–89 (1993) (finding no merit to an overbreadth argument that the possibility of enhanced sentences based on prior racially motivated speech or associations constitutes an impermissible chill on free speech)). Manufacturing a dietary supplement in a manner that violates the CGMP requirements causes the product to be adulterated, and therefore, unlawful.

The fact that a manufacturer may not stay in business, or elects not to enter business, due to: (1) Our implementation of CGMP requirements or (2) our enforcement against a product that violates CGMP requirements, does not mean that we are somehow prohibiting speech. In any event, there is no First Amendment protection for speech that concerns unlawful activity under the first prong of the test set out in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557 (1980). Therefore, the comment's suggestion that there is elimination of speech based on the rulemaking is not supportable. The requirements in the final rule do not infringe on a manufacturer's right to lawfully label and market a dietary supplement.

VI. What Comments Did We Receive on the General Provisions? (Subpart A)

A. Organization of Final Subpart A

Proposed subpart A contained five provisions regarding the scope of the proposed rule, definitions, and exclusions. Table 2 of this document lists the sections in final subpart A and identifies the proposed sections that form the basis of the final rule.

TABLE 2.—DERIVATION OF SECTIONS IN FINAL SUBPART A

Final Rule	2003 CGMP Proposal
§ 111.1 Who is subject to this part?	§ 111.1
§ 111.3 what definitions apply to this part?	§ 111.3
§ 111.5 Do other statutory provisions and regulations apply?	§ 111.5

B. Who Is Subject to This Part? (Final § 111.1)

Section 111.1 explains who is subject to the dietary supplement CGMP requirements. In brief, final § 111.1(a) states that you are subject to the dietary supplement CGMP requirements if you manufacture, package, label, or hold a dietary supplement. This requirement includes a dietary supplement you manufacture but that is packaged or labeled by another person, and a dietary supplement that is imported, offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. Final § 111.1(b), however, excludes certain persons from the rule. Specifically, § 111.1(b) states that the requirements pertaining to holding dietary supplements do not apply to you if you are holding those dietary supplements at a retail establishment for the sole purpose of direct retail sale to individual consumers. This section also states that a retail establishment does not include a warehouse or other storage facility for a retailer or a warehouse or other storage facility that sells directly to individual consumers.

This exclusion represents specific changes sought by the comments. We provide detail on the comments and our reasons for revising final § 111.1 in the following paragraphs.

(Comment 26) Some comments interpret the proposal as not applying to persons who perform labeling operations. For example, one comment claims that proposed § 111.35(e), which would require manufacturers, packagers, and persons who hold dietary supplements to establish specifications, did not apply to ''labelers'' because the proposed definition of ''you'' did not expressly mention persons who label dietary supplements.

(Response) We disagree with the comments. Various provisions in the proposal expressly mentioned or pertained to labels and labeling operations (see, e.g., proposed §§ 111.20(c)(6) (which would require your physical plant to have separate or defined areas for packaging and label operations), 111.30(a) (which would impose certain requirements on automatic, mechanical, or electronic equipment used to ''manufacture, package, label, and hold'' a dietary supplement), 111.35(a) (which would require you to implement a system of production and process controls that cover, among other things, all stages of labeling dietary supplements), 111.37(a) (which would require you to use a quality control unit to ensure, among other things, your label operations are performed in a manner that prevents adulteration and misbranding), 111.40(b) and (c) (which would impose certain requirements on packaging and labels you receive and on persons who perform label requirements), and 111.70 (which would impose various requirements on packaging and label operations)). Although the proposed definition of ''you'' and proposed § 111.1 did not include the word ''label'' or ''labeling,'' we considered label operations to be part of a broader manufacturing process, and it would be illogical to interpret the proposal's specific references to label operations as somehow being inapplicable to labelers simply because a proposed definition of ''you'' or a general ''scope'' provision did not mention labels or otherwise distinguish label operations from the broader context of manufacturing.

In any case, to correct such misinterpretation, we have revised § 111.1 to include the word ''label.'' Thus, under final § 111.1(a), you are subject to the dietary supplement CGMP requirements if you ''manufacture, package, label, or hold a dietary supplement.'' We also have made corresponding changes to other sections in this final rule; for example, we have revised the definition of ''you'' in final § 111.3 to state that ''you'' means ''a person who manufactures, packages, labels, or holds'' a dietary supplement, and we also have inserted the word ''labeling'' in the title to this final rule. We have not explained this change in the preamble each time it is made in the codified provision.

In addition, we refer to ''label'' and ''labeling'' in the context of CGMP requirements related to operations for ensuring the correct label is on the product. To help clarify that we are referring to labeling requirements in this final rule for labeling operations and not, for example, to the labeling requirements in part 101, we inserted the word ''operations'' in the title of part 111 to read ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.''

(Comment 27) Several comments ask for clarification about the rule's applicability to different types of businesses and practices. Some comments ask for a clear listing of who is subject to the rule, stating that it is difficult to apply the rule's specific provisions. According to these comments, the rule's level of detail and inflexibility does not account for variations in manufacturing needs within the entire industry.

Several comments on various proposed sections ask who would be responsible for complying with CGMP requirements if more than one party was involved in the manufacturing, packaging, labeling, or holding of the dietary supplement. For example, some comments ask whether consultants are subject to a specific proposed section; others ask who would be responsible if a firm employed another firm to handle packaging or labeling operations.

Other comments request clarification regarding the rule's applicability to distributors. Some comments claim that a person who holds and sells packaged products should not be subject to dietary supplement CGMP requirements. Other comments state that dietary supplement CGMPs should apply to distributors as well as

manufacturers. These comments assert many supplement distributors are merely marketers who employ contract manufacturers. The comments said that, because marketers are the parties providing supplements to consumers, we should hold marketers responsible for their products and require marketers to ensure that their contract manufacturers adhere to CGMP requirements. These comments argue we should not permit marketers to transfer their responsibilities in delivering safe supplements. Other comments assert questions about the rule's applicability are underscored by typical dietary supplement labeling practices where the contact information listed on the product label pertains to the distributor/marketer instead of the actual manufacturer.

Collectively, these comments raise a basic question as to which party or parties are responsible for complying with the dietary supplement CGMP requirements where more than one party is involved in the manufacture, packaging, labeling, or holding of that dietary supplement.

(Response) In the 2003 CGMP Proposal, we stated that it would apply to a wide variety of activities associated with the manufacture, packaging, and holding of a dietary supplement, including labeling, testing, quality control, holding, and distribution (68 FR 12157 at 12175). We stated under proposed part 111 you would need to comply with those regulations directly applicable to the operations that you perform and provided examples (id.). All activities may not be performed by the same person. For example, a manufacturer may contract with another firm to package and label the dietary supplement in the containers used for distribution to consumers. Alternatively, a distributor may contract with one firm to manufacture a dietary supplement, and another firm to package and label the dietary supplement that the distributor ultimately distributes under its own name.

Under this final rule, you must comply with the CGMP requirements that apply to your operations related to the manufacture, packaging, labeling, and holding of dietary supplements. It is not practical to list all possible contractual relationships that persons may enter into in the manufacture of a dietary supplement, or to list all businesses or practices that may be subject to the requirements of this final rule in order for persons to know whether they are subject to requirements of this final rule. To provide additional clarity about how this rule may apply to various persons, we provide some examples in the following paragraphs.

A manufacturer that manufactures a dietary supplement, and then packages and labels and distributes the dietary supplement, is subject to all the requirements in this final rule. If that manufacturer contracts with another person to package and label the dietary supplement, then the packager/labeler is responsible for complying with the requirements for packaging and labeling operations, in addition to other relevant requirements. The packager/labeler, in this example, would need to comply, not only with the specific requirements related to packaging and labeling operations in subpart L, but also with the general requirements related to personnel, physical plant, quality control, and other requirements that apply to that firm's operations. However the packager/labeler would not need to comply with requirements that do not apply to it; for example, the packager/relabeler would not have to conduct testing on the finished batch of dietary supplement since it does not manufacture the finished batch of dietary supplement.

A manufacturer who contracts with a person to do packaging and labeling, but who later distributes the packaged and labeled product, is ultimately responsible for the dietary supplement it releases for distribution. The manufacturer would be responsible for the CGMP requirements for the operations that it performs, including those related to the release of the product for distribution. For example, the manufacturer must determine whether the packaged and labeled dietary supplement it receives from the packager/labeler conforms to applicable specifications (final § 111.127(d)), and must approve the release of the packaged and labeled dietary supplement for distribution (final § 111.127(h)). Although the manufacturer is not performing the specific activities related to the packaging and labeling operations done by another person, the manufacturer has an obligation to know what and how such activities are performed so that it can make decisions related to whether the packaged and labeled product conforms to applicable specifications and whether to approve and release the product for distribution.

Some manufacturers may sell their finished batch of dietary supplement to a packager/labeler that the packager/labeler may package, label, and then hold and distribute. The manufacturer and packager/labeler would each be responsible for complying with the applicable CGMP requirements related to the operations that they perform. The manufacturer would not be responsible for the oversight of the packager/labeler, since the packager/labeler is not under the control of the manufacturer and has control over the release of the packaged and labeled dietary supplement.

A manufacturer may decide to hire a contractor or a consultant for specific operations within the scope of the manufacturer's responsibilities under the final rule. For example, a manufacturer may hire a person to calibrate its equipment. The manufacturer is responsible for complying with the requirements related to its responsibilities, e.g., calibration requirements in this example, even though the manufacturer has hired another person to perform that job task.

In another example, a distributor who purchases a packaged and labeled dietary supplement and who then holds the product in a warehouse for distribution to another physical location is subject to the requirements related to its operations. The codified uses the word ''hold'' since it is a broad term which encompasses the activities of a distributor. Thus, the distributor would be responsible for complying with requirements in subpart M, *Holding and Distributing*, in addition to other requirements related to its operations (e.g., *Personnel*, *Physical Plant and Grounds*).

In cases where a distributor contracts with a manufacturer to manufacture a dietary supplement that the distributor then distributes under its own label, the distributor has an obligation to know what and how manufacturing activities are performed so that the distributor can make decisions related to whether the packaged and labeled product conforms to its established specifications and whether to approve and release the product for distribution.

(Comment 28) Some comments state that the proposed rule requirements would require the manufacturer to report adverse events to us, but would not require those who distribute the product and whose name is likely to be on the product label, to report adverse events to us. The comments state that reports of adverse events submitted by consumers to those who distribute, but do not make, dietary supplements could be hidden from the public if such persons are not required to submit those reports to us.

(Response) The comments may have misinterpreted the proposed rule. The requirement to review and investigate a product complaint is distinct from any report about the product complaint to

us. Reporting a complaint to us is not covered by these CGMP requirements and would be voluntary, unless the complaint is subject to the statutorily mandated reporting requirements for ''significant adverse events'' pursuant to the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), signed into law on December 22, 2006 (see discussion in section XX of this document).

Under the procedures that are set forth in subpart O, *Product Complaints* (see section XX of this document), a distributor and a manufacturer are both subject to the requirements related to the review and investigation of a product complaint that they receive.

(Comment 29) Some comments argue against including minimum CGMPs necessary for activities related to manufacturing, packaging, labeling, or holding dietary ingredients in the final rule. Several comments argue the proposed rule is overly broad and inconsistent with congressional intent. These comments question whether Congress intended that CGMP apply to persons involved in the manufacture, packaging, labeling, and holding of dietary ingredients. The comments also argue that, if the rule applies to dietary ingredient manufacturers, we would be establishing precedent and that we lack legal authority to regulate ingredients rather than the finished products themselves. The comments state that neither food CGMP nor drug CGMP offers precedent or guidance on regulating ingredients. The comments argue those who provide dietary ingredients should be subject to the existing general food CGMP requirements in part 110 rather than to the dietary supplement CGMP requirements.

Several comments argue that many dietary ingredients are used in regular foods and in drugs as well as in dietary supplements. The comments argue, for some dietary ingredients, their use in dietary supplements represents a very small percentage of the dietary ingredient's worldwide usage. The comments say we should allow those who deal only with dietary ingredients to operate under one set of regulations, such as the general food CGMP requirements in part 110. According to these comments, we have not demonstrated either a failure of the current system or a compelling need to create different regulations for raw materials common to both the food and dietary supplement industries. The comments would revise the title of part 111 and proposed § 111.1 and make conforming revisions throughout the proposed rule to limit the rule's applicability to dietary supplements.

In contrast, other comments say the rule should apply to dietary ingredient manufacturers as well as to dietary supplement manufacturers. The comments state that excluding those who provide or supply dietary ingredients would mean those who have the greatest expertise in these goods would not be subject to dietary supplement CGMP requirements and thus fail to cover a crucial step in preventing the adulteration or contamination of dietary supplements. The comments argue that, for some dietary ingredients (especially raw botanical and agricultural goods), the most critical point in ensuring an ingredient's quality and purity is at time of harvest or creation, and that this is particularly true with new or original ingredients.

The comments state problems with dietary supplements often arise from substandard ingredients, and the difficulty in testing the properties of some botanical and other dietary ingredients at the in-process or finished product stage makes it necessary to include dietary ingredient manufacturers in the final rule. Furthermore, these comments assert a flexible testing scheme that they recommend (which emphasizes establishing specifications for components, relying on certificates of analysis from qualified suppliers, qualifying component suppliers, and establishing written procedures, with testing of finished batches serving as a check on the overall manufacturing process) makes it important to regulate dietary ingredient manufacturers.

Other comments suggest we issue a separate or modified set of CGMP requirements that would apply to persons who manufacture, package, label, or hold dietary ingredients. These comments say the proposed rule does not work for all dietary ingredients, especially those converted from non-food grade to food grade during the manufacturing process. These comments said the rule should be modified for dietary ingredients.

(Response) Two issues seem to be raised by these comments: (1) Whether dietary ingredients are within the scope of this final rule and (2) whether dietary ingredient manufacturers are subject to this final rule. Dietary ingredients are included within the scope of this final rule but dietary ingredient manufacturers are not necessarily subject to this rule. The definition of ''component'' in this final rule includes ''any substance intended for use in the manufacture of a dietary supplement including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients (as described in section 201(ff) of the act) and other ingredients'' (final § 111.3). The proposed rule, § 111.3, recognized that ''dietary ingredients'' are ''components'' (68 FR 12157 at 12176) (describing how dietary ingredients would fall within the proposed definition of ''component'').

There are specific requirements in this final rule that relate to components, and thus dietary ingredients, that are used in the manufacture of a dietary supplement. For example, final § 111.70(b) requires you to establish certain component specifications. Such requirements would include specifications for dietary ingredients as ''components.'' It is important to control the components used in the manufacture of dietary supplements to ensure consistency and to ensure the quality of the dietary supplement. Since dietary ingredients are considered components, the various requirements apply to dietary ingredients as part of the production and process control. Therefore, we disagree to the extent comments were suggesting that there should be no CGMP requirements related to the dietary ingredients used by a manufacturer in the manufacture of dietary supplements.

Dietary ingredients are included within the meaning of ''component.'' In those requirements in the proposed rule where ''component'' encompasses ''dietary ingredient'' we are, in the final rule, removing ''dietary ingredient'' in those requirements and only refer to ''component.'' Given the scope of the final rule, it is redundant to refer to both ''component'' and ''dietary ingredient'' where the latter is subsumed in the former.

In response to comments that questioned the need to include manufacturers of dietary ingredients within the scope of part 111, we have made changes to the scope of the rule, as applied to dietary ingredient manufacturers. As we explain more fully in our discussion of final §§ 111.70, 111.73, 111.75, and 111.77 (see section X of this document), after considering comments about the overall production and process control system, we revised the final rule's approach to ensuring product quality. This approach emphasizes that it is important to ensure the quality of the dietary supplement throughout the production and process control system. This approach emphasizes establishing specifications for components and ensuring those specifications are met.

You may rely on a certificate of analysis for specifications (except for the identity of the dietary ingredient) only if you satisfy certain criteria, which include qualifying the supplier of the components. With this approach, the goal of ensuring the quality of dietary supplements can be achieved without applying the rule specifically to persons who manufacture, package, label, or hold dietary ingredients that will be further processed as a dietary supplement by other persons.

Consequently, we revised § 111.1 by deleting ''dietary ingredient.'' Therefore, those who manufacture, package, label, or hold dietary ingredients are not subject to the final rule. To illustrate, assume you manufacture a dietary ingredient and sell that bulk dietary ingredient to Company X. Company X then utilizes the bulk dietary ingredient in a dietary supplement. Under final § 111.1(a), you would not be subject to these dietary supplement CGMP requirements because you are not manufacturing a dietary supplement, rather you are manufacturing a dietary ingredient for further incorporation into a dietary supplement by Company X. If, however, you sell herbs in bulk to Company X, and Company X simply packages the herbs into smaller units for sale as a dietary supplement, you would be subject to the dietary supplement CGMP requirements because you are manufacturing a dietary supplement that Company X is simply packaging and labeling, and not further processing into a dietary supplement. In other words, in the latter example, you would have acted as a manufacturer whose finished product is simply repackaged or relabeled.

Under final § 111.1(a) persons engaged solely in activities relating to the harvesting, storage, or distribution of raw agricultural commodities that will be incorporated into a dietary supplement by others are not included within the scope of the rule as a dietary supplement manufacturer. This is because those persons simply ''supply'' a component (i.e., the raw agricultural commodity) that another person will process into a dietary supplement; thus you do not manufacture, package, label, or hold a dietary supplement.

Note, too, that if you manufacture and supply a component directly to consumers as a dietary supplement, you would be considered a dietary supplement manufacturer within the scope of final § 111.1(a). Likewise, if you manufacture a component and sell part of the batch to another person who, in turn, will further process the component as a dietary supplement and sell the remainder of the batch to consumers as a dietary supplement, you would be subject to the dietary supplement CGMP requirements, as a manufacturer, for the product sold to consumers and not subject to an exclusion under final § 111.1(b), discussed in this section. In other words, final § 111.1(a) refers to the nature of your activity, and simply engaging in some activities that do not bring you within the scope of the final rule does not necessarily mean that all your activities are outside the scope of the final rule.

We do not agree, as some comments suggested, that we need to issue a separate or modified set of CGMP requirements for dietary ingredients. That is because there are adequate controls established in this final rule for the use of dietary ingredients used by the manufacturer of a dietary supplement. However, if you manufacture, package, label, or hold dietary ingredients that will be further processed as a dietary supplement by another person, you must comply with food CGMP requirements in part 110. A dietary ingredient is a food under section 201(f) of the act, as a food, or as a component of food. Because the final rule gives manufacturers an incentive to qualify suppliers of dietary ingredients, persons who manufacture, package, label, or hold dietary ingredients may wish to familiarize themselves with these dietary supplement CGMP requirements and use them in manufacturing, packing, labeling, or holding operations for dietary ingredients.

(Comment 30) Some comments argue if the final rule ultimately covers dietary ingredient suppliers then we should clarify what constitutes a ''consumer.'' According to these comments, dietary ingredient suppliers do not typically supply their products directly to those individuals who will ultimately consume or ingest them. Thus, ''consumers'' of dietary ingredients are other companies, not individuals. The comments express concern about the possible application of proposed § 111.95 which would require procedures for handling complaints.

(Response) The final rule applies only to persons who manufacture, package, label, or hold dietary supplements and are not subject to an exclusion in final § 111.1. However, as explained in the previous response to comment 29, if a dietary ingredient manufacturer also supplies or sells a dietary ingredient as a dietary supplement, such a manufacturer would be subject to final § 111.1(a) and subject to all relevant dietary supplement CGMP requirements.

Some comments expressed concern about dietary ingredient manufacturers having to comply with proposed § 111.95 on product complaints. If a dietary ingredient manufacturer receives a product complaint, we encourage the manufacturer to evaluate the complaint to determine if it may involve a problem with the manufacture of the dietary ingredient. In addition, we encourage the dietary ingredient manufacturer to notify the dietary supplement manufacturer so that it can review the complaint and investigate, as needed.

(Comment 31) Several comments question the proposal's applicability to persons who sell packaged products or seek clarification as to whether the rule applies to dietary supplement manufacturers that operate from homes and those that distribute product to other distributors.

(Response) To the extent that the comments question whether retailers or individuals who sell dietary supplements directly to individual consumers are subject to the dietary supplement CGMP requirements, we have revised the final rule by creating a new § 111.1(b) which states that: ''The requirements pertaining to holding dietary supplements do not apply to you if you are holding those dietary supplements at a retail establishment for the sole purpose of direct retail sale to individual consumers. A retail establishment does not include a warehouse or other storage facility for a retailer or a warehouse or other storage facility that sells directly to individual consumers. '' This means, for example, if you operate a storefront retail establishment where you stock dietary supplements on your shelves for purchase by individual consumers, we do not consider you to be ''holding'' those dietary supplements in a manner that would require you to comply with the holding provisions in this final rule. Sale to individual consumers, where you are not storing bulk dietary supplements as one would in a warehouse or storage facility, does not fall within the manufacturing, packaging, labeling, or holding activities that would subject you to dietary supplement CGMP requirements.

However, if you operate storefront retail establishments, and those retail establishments obtain their stocks from your warehouse, we would consider your warehouse operations to be ''holding'' dietary supplements and expect your warehouse operations to comply with the rule's holding requirements. Such distribution is no different than other warehouse operations that are normally subject to CGMP requirements. Consequently, to

distinguish between ''holding'' dietary supplements for retail sale to consumers and ''holding'' dietary supplements in a warehouse for further distribution, final § 111.1(b) limits the exclusion to persons holding dietary supplements ''at a retail establishment for the sole purpose of direct retail sale to individual consumers.'' Final § 111.1(b) also makes it clear that a retail establishment does not include a warehouse or other storage facility that a retailer uses to hold the dietary supplements or an operation that sells directly to consumers, but that itself distributes the product to the consumer from a warehouse or storage facility and not from a storefront retail establishment.

(Comment 32) Many comments question the rule's applicability to various practitioners such as herbalists, acupuncturists, naturopaths, and other health care providers who prepare individualized herbal formulas for specific individuals on a case-by-case basis. Most comments say such practitioners should not be covered by the rule. These comments give various reasons to justify their position, including:

- These practitioners do not broadly sell products;
- These practitioners make very small quantities of individualized formulas, and can therefore be very selective as to the quality of ingredients used;
- The testing and storage requirements of each finished batch cannot apply to a small dispensary where several different modified herbal formulas are prepared each day;
- Based on the projected costs to implement CGMPs, it would be virtually impossible for an individual practitioner or university clinic to develop the necessary quality control unit, maintain reserve samples, maintain the required paperwork, or retrofit clinics to comply with the rule;
- Many States regulate or license these practitioners, so further Federal regulation is unnecessary;
- Some practitioners do not consider themselves to be manufacturers;
- In an analogous situation, compounding pharmacists are not required to comply with drug CGMPs; and
- Despite the growing number of such practitioners, there is no proof that greater harm has occurred to the general public from the herbs these practitioners sell.

(Response) We stated in the 2003 CGMP Proposal (68 FR 12157 at 12175) that we declined to exempt herbalist practitioners from the proposed rule. We continue to believe that the risks of adulteration are not eliminated just because the practitioner is an herbalist, and therefore, such an exemption should not be included in this final rule. However, after further consideration, we have determined that it would be appropriate for us to consider the exercise of our enforcement discretion in deciding whether to apply the requirements of this final rule to certain health care practitioners, such as herbalists, acupuncturists, naturopaths, and other related health care providers.

We find it noteworthy that the comments identified two potential safeguards that could support the exercise of our enforcement discretion on whether to apply the requirements of the final rule to certain practitioners: (1) Adequate training in the professional practice and (2) an individual client and practitioner relationship. For example, comments claimed that the practitioners receive adequate training to formulate dietary supplements and that they provide the dietary supplements to individuals in the course of a one-on-one consultation on the premises of the practitioner. One comment from a practitioner states that she received her training from an accredited 4-year university and it included didactic and clinical training in acupuncture and Chinese herbs. Another comment from an organization provides detailed training guidelines for practitioners, including 1,600 hours of training, 400 hours of which should include clinical work. Moreover, many comments also assert that the practitioners are different from dietary supplement manufacturers because they formulate the dietary supplements in the course of a one-on-one consultation at their premises. That enables them to ensure the formulations are made to meet the specific needs of the individuals.

We believe that a one-on-one consultation by a practitioner who is adequately trained in their profession may not necessitate the same types of controls as we are establishing in this final rule for manufacturing activities that are on a larger scale. Such a practitioner may make some formulations in advance of the consultation and still make the formulations in very limited quantities for the individual client. We believe that it would be appropriate to consider the exercise of our enforcement discretion, on a case-by-case basis, to determine whether to apply the requirements of this final rule to such persons.

We do not expect the number of those subject to the consideration of our enforcement discretion to be very large. Many products that are manufactured by practitioners would not necessarily be considered to be dietary supplements (e.g., certain products used by traditional Asian medicine practitioners). Further, we are not considering exercising our enforcement discretion with respect to practitioners who prepare batches of herbs and sell them to individual consumers without determining whether the dietary supplement is appropriate for each consumer's needs in a one-on-one personal consultation, or those that prepare batches of a dietary supplement for which there is a known or suspected safety concern.

(Comment 33) Several comments asked us to exempt academic institutions that provide training for therapeutic disciplines that use, for example, herbal formulas in their practice regardless of whether the dietary supplements they produce enter into interstate commerce. Specifically, these comments would revise the final rule to state that it does not apply ''to academic institutions that provide training in dispensing of nutritional or herbal products and formulas related to courses in therapeutic disciplines that provide such products and formulas as a part of their therapy, for example, naturopathy, herbalism, traditional Chinese medicine, and acupuncture.''

(Response) Similar to what we stated in response to comment 32, we believe that it may be appropriate to consider the exercise of our enforcement discretion in circumstances where an academic institution's actions are similar to those of a practitioner who is adequately trained in their profession and who provides dietary supplements within the context of an individual client and practitioner relationship. In general, it is not our policy to inspect an academic institution that provides training for therapeutic disciplines that use, for example, dietary supplements in their practice. We intend to consider the exercise of our enforcement discretion in those situations where there is a one-on-one consultation that includes a practitioner with adequate training. We intend to issue guidance to further clarify how the agency intends to exercise its enforcement discretion on the application of this final rule to certain academic institutions.

(Comment 34) Several comments discuss the position taken by certain nations, notably Australia and Canada, that have developed CGMP requirements and related guidance for botanicals. According to these comments, these nations recognize that there are various types of practitioners who sell herbs and herbal preparations in a clinical setting, and do not consider such persons to be manufacturers. The

comments ask us to follow the example of these nations.

(Response) We intend to consider the positions taken by other nations to inform us in our decisionmaking in any future guidance on how we intend to exercise our enforcement discretion on the application of this final rule to certain practitioners.

(Comment 35) Many comments say we should define when a dietary supplement will be said to have entered interstate commerce. The comments state herbal practitioners (and academic institutions) often purchase source herbs from outside their State, even if they prepare these herbs for their specific customers within the State. These comments request we clarify that the rule does not apply to herbs purchased out of State if prepared for local use. Other comments request clarification regarding clients who have moved across State lines, yet maintain a relationship with an herbalist practitioner.

(Response) In section V of this document we explain the interstate and intrastate issue related to the final rule.

(Comment 36) A few comments assert individual practitioners and practitioner organizations often are unaware of the opportunity to comment on CGMP or regulatory issues. Therefore, the comments say these practitioners and organizations often fail to provide comment or otherwise participate in rulemaking and say we should give these practitioners and practitioner organizations a chance to comment.

(Response) We provided many opportunities for comment and, therefore, we decline to adopt the comments' suggestion. As we discuss in section I of this document, we published an ANPRM concerning dietary supplement CGMPs on February 6, 1997 (62 FR 5700); the 1997 ANPRM provided an opportunity for public comment. On March 7, 2003, we issued a Talk Paper, along with other background documents, announcing the issuance of a proposed dietary supplement CGMP rule. We made the proposed rule available when it went on display (before it published) in the **Federal Register** on March 13, 2003 (68 FR 12157), and, again, provided an opportunity for public comment. We also held public meetings on April 29, 2003, in College Park, MD and on May 6, 2003, in Oakland, CA. We also held a public meeting (via satellite downlink) on May 9, 2003, with viewing sites at our district and regional offices throughout the country. Thus, we provided numerous opportunities for interested persons to learn about the rule and to submit comments or otherwise participate in the rulemaking process. Consequently, we decline to provide yet another opportunity for comment.

(Comment 37) The preamble to the 2003 CGMP Proposal noted that comments submitted in response to our 1997 ANPRM state we should not distinguish between dietary supplements made in the United States and those made in a foreign country (68 FR 12157 at 12174). Although we agreed with the comments and made no distinction between foreign and domestic firms in the proposed rule, we invited comment on how we might ensure dietary ingredients and dietary supplements exported to the United States have been manufactured, packaged, labeled, and held consistent with part 111 (68 FR 12157 at 12175).

Several comments argue the rule should apply to foreign firms as well as domestic manufacturers to ensure a ''level playing field'' and to protect American consumers. Some comments say we should work with foreign countries to harmonize our requirements and thus avoid potential trade disputes under international trade agreements such as the General Agreement on Tariffs and Trade. Other comments suggest compliance by foreign firms could be achieved through the use of third party certification programs, such as the dietary supplement verification program administered by USP, or the adoption of importer verification provisions similar to those used in our HACCP requirements for seafood (see § 123.12).

In contrast, another comment says we should inspect foreign firms to ensure compliance, whereas other comments claim we lack jurisdiction over foreign firms.

(Response) We are amending proposed § 111.1 to clarify the regulation's applicability to foreign firms. We explain in this section how we may enforce the rule against foreign firms. We, however, are not making any changes in response to the comments calling for the harmonization of the rule with foreign rules because this request is beyond the scope of the final rule.

In response to comments, and for clarification, we have revised final § 111.1(a) to clarify that the regulation applies to the extent that you manufacture, package, label, or hold a dietary supplement, including a dietary supplement imported or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

With respect to the comments requesting that we make clear our position for enforcing the rule against foreign firms, we explain our position as follows. Section 801(a) of the act (21 U.S.C. 381a) authorizes us to refuse admission of an imported food if it appears from the examination of such samples or otherwise that such article is, among other things, adulterated. A foreign firm's refusal to allow us to obtain records via an inspection for CGMP purposes, as required by final § 111.610 (for the dietary supplements the foreign firm offers for import into the United States), would create the appearance that such imported dietary supplements are adulterated under section 402(g) of the act, and thus, could lead to a refusal of admission under section 801(a) of the act.

Foreign firms who ship to the United States must operate under conditions that satisfy our regulations, including the requirement that records be made available during the course of an FDA inspection. We note that except in circumstances where there is a public health emergency or we receive information that would indicate the appearance of adulteration of products shipped to the United States, foreign inspections are generally scheduled well, e.g., weeks, in advance. Thus, we believe that taking action under section 801 of the act is appropriate if companies do not accommodate our inspectional request.

C. What Definitions Apply to This Part? (Final § 111.3)

Section 111.3 defines various terms that we use in the final rule and notes that definitions or interpretations of terms in section 201 of the act also apply. In general, we adopted the definitions that we proposed, although, in some cases, we deleted words or concepts as a result of other changes we made to the final rule. We have added a definition of ''quality'' for purposes only of this final rule.

A recurring change we made is the deletion of the words ''dietary ingredient'' in several definitions. In some cases, the use of the words ''dietary ingredient'' was redundant to the use of ''component'' and thus not necessary in the final rule. Because a ''dietary ingredient'' is subsumed within the definition of ''component,'' as explained in our response to comment 29, we deleted ''dietary ingredient'' in those definitions where ''component'' was used to avoid redundancy.

In other provisions, we deleted ''dietary ingredient'' from the definition because the use of those words was no longer necessary given the narrowing of the scope of the rule as it applies to dietary ingredient manufacturers (explained in the response to comments

29 and 30). For example, we deleted ''dietary ingredient'' from the proposed definition of ''ingredient'' that referred to the ''manufacture of a dietary ingredient or dietary supplement'' and the ''finished batch of the dietary ingredient or dietary supplement.'' We did not need to state ''manufacture of the dietary ingredient'' or refer to ''finished batch of dietary ingredient'' because dietary ingredient manufacturers that only supply such ingredients to other persons for processing into a dietary supplement are not subject to the final rule.

We discuss changes to the definitions, other than the changes we have made globally such as the deletion of ''dietary ingredients,'' the change from ''include, but not limited to'' to ''includes'' or ''include,'' the addition of labels and labeling, and the deletion of the word ''quality'' from the phrase ''identity, purity, quality, strength, and composition,'' as well as comments asking us to define more terms or to delete certain definitions, in more detail in the following paragraphs.

1. Actual Yield

The final rule defines ''actual yield'' as ''the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular dietary supplement.''

We received no substantive comments to the proposed definition.

2. Batch

The final rule defines ''batch'' as ''a specific quantity of a dietary supplement that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.''

This definition differs from the proposed definition of ''batch'' by stating that a batch is a specific quantity of a dietary supplement that is ''uniform.''

We inserted the word ''uniform'' in response to comments asking that we define ''lot'' to be consistent with ''batch.'' We explain our reasons for harmonizing the definitions and for inserting ''uniform'' into the definition of ''batch'' in the response to comment 42 of this document.

We discuss the comments on our proposed definition of ''batch'' and our changes to the definition in our responses to the following comments.

(Comment 38) Several comments ask us to clarify what the ''same cycle of manufacture'' is in the definition of ''batch.'' One comment asks if it meant the same product made with the same lot(s) of raw materials regardless of how many days it took to produce the batch, or if it meant a quantity produced in 1 day. The comment also asks whether batches produced on consecutive days, using the same formula, can be considered to be the same batch with respect to the proposed testing requirements if the quality control unit determined that different lots of raw materials are equivalent (e.g., by meeting all specifications).

(Response) The ''same cycle of manufacture'' refers to a process during which equipment remains dedicated to the manufacture of the batch. The terms do not limit you to any particular time period or require you to operate equipment continuously until you have completed the ''same cycle of manufacture.'' The ''same cycle of manufacture'' also does not limit the number of lots of components you use.

You may consider, as one batch, a product produced using different lots of raw materials where the production of the batch is a continuous process on a dedicated line. However, for each component that you use in the manufacture of the batch of dietary supplement, you would need to establish specifications under final § 111.70, determine whether these specifications are met under final § 111.73, and ensure that these component specifications are met using the criteria under final § 111.75. Further, you may not consider different batches of product produced on consecutive days using the same formula to be the same batch for purposes of testing requirements. The term ''different batches'' suggests that the production is not a continuous process on a dedicated line.

3. Batch Number, Lot Number, or Control Number

The final rule defines these terms as ''any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, and/or holding of a batch or lot of dietary supplements can be determined.''

We received no substantive comments on the definition. We added the word ''and'' before ''or'' to emphasize that the history of each activity must be able to be determined.

4. Component

The final rule defines ''component'' as ''any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients (as defined in section 201(ff) of the act) and other ingredients.''

The definition of component now refers only to the manufacture of a dietary supplement (whereas the proposal also referred to the manufacture of dietary ingredients). We also made a nonsubstantive, editorial revision in the last sentence to put parentheses around the reference to section 201(ff) of the act and to change the word order so that ''component'' includes ''dietary ingredients * * * and other ingredients.'' (The proposed definition had ''components'' including ''ingredients and dietary ingredients.'')

(Comment 39) Some comments would distinguish among ''raw material,'' ''components,'' and ''starting material'' because the comments said that defining ''component'' to include all these materials is confusing. One comment adds that many starting materials are not food grade or approved food ingredients until they have been processed. One comment states the term ''raw material'' is typically used to describe the materials (such as dietary ingredients, fillers, and processing aids) that will be used to make the final product. The comment further states ''component'' is typically used to describe the specific items used to assemble the finished product for the end user. The components would include packaging components such as bottles, caps, and labels, as well as the bulk dietary supplement. This comment also suggests that we use the term ''starting material'' to distinguish substances used in the manufacture of dietary ingredients from substances used in the manufacture of dietary supplements.

(Response) We decline to revise the rule as suggested by the comments. There may be differences in how components are referred to by certain manufacturers and how we refer to it in this final rule. However, for purposes of this final rule we refer to all substances used in the manufacture of dietary supplements as ''components,'' whether or not those substances appear in the finished product.

Please note that, although ingredients are ''components'' under our definition, not all components are ingredients. For example, a solvent used to make an herbal extract is not an ingredient when it is removed from the extract by a process such as drying, because the solvent was not intended to be present in the finished dietary supplement. However, the solvent would be a ''component'' because it was used in the manufacture of the dietary supplement.

As for materials that might not be food grade or approved food ingredients until processing, see the discussion in response to comment 240 in section XII of this document.

(Comment 40) Several comments express concern that ''component'' could be interpreted to mean any constituent present in a botanical extract or other natural product. The comments say a single botanical can contain tens of thousands of constituents or metabolites and that chemists have not identified all constituents of a single botanical. According to the comments, the cost of testing for all constituents would exceed a product's total annual revenues.

(Response) In general, we would consider the botanical extract or the other natural product to be the ''component'' as defined in this final rule rather than consider that all the various chemical substances contained in the botanical extract or other natural product are components. Thus, if you are manufacturing a dietary supplement that is intended to provide a certain substance (e.g., vitamin C) and you add a natural product which is intended to supply the vitamin C (e.g., vitamin C in the form of rosehips), we would consider the natural product (e.g. rosehips that contain a certain amount of vitamin C) to be a component which must be listed in the master manufacturing record. The component specifications for the rosehips must include a specification for the strength of the substance (e.g., vitamin C) in whatever amount you determine is necessary to meet the specification for the strength of the vitamin C in the finished batch of dietary supplement. Under final § 111.70, we expect you to establish specifications for the natural product and ensure that the specifications are met. As an example relevant to an extract, if you are manufacturing a dietary supplement that is intended to provide a certain amount of vitamin C that derives from the natural product rosehips, and the substance that you purchase from a supplier to add as a component is a purified extract of rosehips (rather than rosehips themselves), we would consider the purified extract to be a component (as an ingredient). The component specifications for the purified extract must include a specification for the strength of the substance (i.e., vitamin C) in whatever amount you determine is necessary to meet the specification for the strength of the vitamin C in the finished batch of dietary supplement. However, in this example ''rosehips'' would not be considered a component, because ''rosehips'' is not what you added.

5. Contact Surface

The final rule defines ''contact surface'' as ''any surface that contacts a component or dietary supplement, and those surfaces from which drainage onto the component or dietary supplement, or onto surfaces that contact the component or dietary supplement, occurs during the normal course of operations.'' The final rule lists containers, utensils, tables, contact surfaces of equipment, and packaging as examples of ''contact surfaces.''

We did not receive any substantive comments on the proposed definition. We deleted ''ordinarily'' from ''ordinarily occurs during the normal course of operations'' because ''ordinarily'' is redundant to ''normal.''

6. Ingredient

The final rule defines ''ingredient'' as ''any substance that is used in the manufacture of a dietary supplement and that is intended to be present in the finished batch of the dietary supplement. An ingredient includes, but is not necessarily limited to, a dietary ingredient as defined in section 201(ff) of the act.'' We did not receive any substantive comments on this definition. We made a nonsubstantive, editorial change to replace ''finished dietary supplement'' with ''finished batch of the dietary supplement.''

(Comment 41) One comment says we should define ''ingredient'' better to ensure consistent interpretation of CGMP at all levels throughout the dietary supplement industry.

(Response) We disagree with the comment. We believe the definition is adequate, including as it does both dietary ingredients as described in section 201(ff) of the act and other ingredients that do not fit that description, such as an emulsifier used to establish a uniform dispersion in a liquid dietary supplement or a color additive used to color a capsule. Moreover, the comment did not explain or specify which aspects of the proposed definition should be revised or explain why the proposed definition would lead to inconsistent interpretations of CGMP.

7. In-Process Material

The final rule defines ''in-process material'' as ''any material that is fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the manufacture of a dietary supplement.''

We did not receive any substantive comments on the proposed definition.

8. Lot

The final rule defines ''lot'' as ''a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications for identity, purity, strength, and composition; or, in the case of a dietary supplement produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.''

The final rule differs from the proposed definition in that the proposed definition of ''lot'' would have the batch or specific identified portion of a batch be intended to have ''uniform identity, purity, quality, strength, and composition.''

(Comment 42) One comment agrees with the proposed definition for ''lot,'' but several other comments would revise the definition to be more consistent with the proposed definition of ''batch.'' Specifically, the comments note the proposed definition of ''batch'' would refer to a quantity of dietary supplement that is ''intended to meet specifications for identity, purity, quality, strength and composition,'' whereas the proposed definition of ''lot'' would refer to a batch or specific identified portion of a batch that is ''intended to have uniform identity, purity, quality, strength, and composition.'' The comments would revise the definition of ''lot'' by deleting the phrase ''intended to have uniform'' and inserting the phrase ''intended to meet specifications for'' in order to make the definitions of ''batch'' and ''lot'' consistent.

(Response) We agree that the definitions for ''batch'' and ''lot'' should be consistent, but we disagree with the comments' suggestion to delete the term ''uniform'' from the definition of ''lot.'' The attributes of a lot or batch should be uniform throughout the lot or batch and meet established specifications for those attributes. If samples from a lot or batch were tested for appropriate specifications of identity, purity, strength, and composition, the attributes should be consistent throughout the sample and be uniform from sample to sample regardless of whether the test samples are taken from the beginning, middle, or end of the lot or batch. Consequently, we revised the definition of ''lot'' to state, in relevant part, that a ''lot'' is a batch or specific identified portion of a batch that ''is uniform and that is intended to meet specifications

for identity, purity, strength, and composition'' or, for dietary supplements produced by a continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.''

Similarly, we revised the definition of ''batch'' so that it states, in relevant part, that a ''batch'' is a specific quantity of a dietary supplement ''that is intended to meet specifications for identity, purity, strength, and composition.''

These revisions make the definitions of ''batch'' and ''lot'' consistent.

9. Microorganisms

The final rule defines ''microorganisms'' as ''yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern.'' It adds that the definition includes species that: (1) May have public health significance; (2) may cause a component or dietary supplement to decompose; (3) indicate that the component or dietary supplement is contaminated with filth; or (4) otherwise may cause the component or dietary supplement to be adulterated.

(Comment 43) One comment would revise the definition to identify specific microorganisms that have public health or sanitary concern (i.e., *Salmonella* species, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*). The comment says this would be consistent with USP requirements.

(Response) We disagree with the comment. A list of specific microorganisms could easily become outdated as new pathogens emerge, and constantly issuing new rules to revise the list would be both inefficient and impractical.

(Comment 44) One comment expresses concern that the proposed definition for microorganisms would include microorganisms that are a natural part of the ecology of all natural products. The comment says certain levels of microorganisms are expected on botanical raw materials (i.e., those naturally occurring or introduced through organic cultivation techniques) and that many do not present a public health risk. The comment expresses concern that nonpathogenic microorganisms that are not a public health risk would be a ''sanitary'' concern that would render a product adulterated. The comment argues there should be little concern about the presence of microorganisms that present no public health consequence, and so we should revise the definition accordingly. The comment further discusses the difficulties in ''sterilizing'' botanicals to render them free of microorganisms associated with insanitary conditions. The comment notes that some international organizations have established ''upper limits'' for these organisms for botanical supplements, which, in the comment's opinion, represent more realistic standards than trying to attain a ''sterile'' botanical supplement.

(Response) We disagree with the comment. We do not interpret the definition of ''microorganism'' as making the presence of nonpathogenic microorganisms that are not a public health risk a ''sanitary concern'' that would render a product adulterated. Instead, we interpret the definition as saying that microorganisms of public health significance and microorganisms presenting sanitary concerns are ''microorganisms'' under this rule. These are the types of microorganisms that may cause a component or dietary supplement to become adulterated.

As for upper limits on microbial contamination, the comment offered no suggested limits, and we decline to establish such limits in this rule. The final rule requires manufacturers to establish limits for those types of contamination that may adulterate or lead to adulteration of components or dietary supplements. Thus, for example, a manufacturer of a botanical dietary supplement would have to determine what, if any, microorganisms are likely or certain to be present and establish limits, as appropriate to prevent adulteration of the finished batch of the dietary supplement.

We have modified the word ''have'' with the word ''may'' to indicate that the determination or evaluation of whether there is a ''public health significance'' is not made after the fact. There does not have to be a factually established determination of public health significance for you to conclude that the microorganisms ''may adulterate'' the dietary supplement. The change from ''could cause'' to ''may cause'' is to be consistent with the previous change to ''may have.''

10. Must

The final rule explains that the word ''must'' is ''used to state a requirement.''

(Comment 45) One comment would revise the definition to say that the term ''must'' be used to state mandatory requirements ''unless shown to be inapplicable or replaced by an alternative demonstrated to provide at least an equivalent level of quality assurance.''

(Response) We decline to revise the rule as suggested by the comment. The comment's revision would undermine the reasons for issuing a rule. Rules create enforceable requirements. It is not clear, nor did the comment discuss, how we could enforce the requirements in this final rule if firms were able to avoid a particular requirement by declaring them to be ''inapplicable'' or substituting alternatives which they felt they had demonstrated were ''at least an equivalent level of quality assurance.'' There would be inconsistency in the general CGMP practices used within the dietary supplement industry and uncertainty as to whether the process and production controls ensure the quality of the dietary supplement. Consequently, we decline to revise the rule as suggested by the comment.

We have, however, made a nonsubstantive, editorial change to the definition so that ''must'' is used to state ''a requirement.'' The proposed definition had referred to ''mandatory requirements.'' Since a requirement by its nature is mandatory, the word ''mandatory'' is unnecessary.

11. Pest

The final rule defines ''pest'' as ''any objectionable insect or other animal, including birds, rodents, flies, mites, and larvae.''

We did not receive any substantive comments on this definition. However, on our own initiative, we made nonsubstantive, editorial changes to delete the words, ''but not limited to'' after ''including'' and to place the word ''animals'' in the singular.

12. Physical Plant

The final rule defines ''physical plant'' as ''all or any part of a building or facility used for or in connection with manufacturing, packaging, labeling, or holding a dietary supplement.''

We received no substantive comments on this definition. The final rule is substantially similar to the proposed rule's definition of ''physical plant.'' We added ''any'' and placed ''part'' in the singular to clarify that individual parts of a building or facility are subject to the CGMP requirements.

13. Product Complaint

The final rule defines ''product complaint'' as ''any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a dietary supplement, that could be related to current good manufacturing practice. Examples of product complaints are: Foul odor, off taste, illness or injury, disintegration time,

color variation, tablet size or size variation, under-filled container, foreign material in a dietary supplement container, improper packaging, mislabeling, or dietary supplements that are superpotent, subpotent, or contain the wrong ingredient, or contain a drug or other contaminant (e.g., bacteria, pesticide, mycotoxin, glass, lead).''

This definition modifies the proposed rule's definition of ''consumer complaint,'' which would define such a complaint as any ''communication that contains any allegation, written or oral, expressing dissatisfaction with the quality of a dietary supplement related to good manufacturing practices. Examples of product quality related to good manufacturing practices are: Foul odor, off taste, superpotent, subpotent, wrong ingredient, drug contaminant, other contaminant (e.g., bacteria, pesticide, mycotoxin, glass, lead), disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a dietary supplement container, improper packaging, or mislabeling. For the purposes of this regulation, a consumer complaint about product quality may or may not include concerns about a possible hazard to health. However, a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient independent of whether the product is produced under good manufacturing practices.''

We explain the reasons for revising the proposed definition in our response to the following comments.

(Comment 46) Some comments would broaden the definition of consumer complaint to include complaints from dietary ingredient suppliers. One comment would change ''consumer complaint'' to ''customer complaint.''

(Response) As discussed in section VI of this document, the final rule does not apply to those who only manufacture dietary ingredients. However, we encourage such firms that receive complaints about a dietary supplement to share those complaints with those in the manufacturing chain associated with that dietary supplement's manufacture so others may take corrective action as needed. Those who engage in the manufacture of a dietary supplement, including manufacturing, packaging, labeling, and holding operations, are responsible for complying with this final rule's product complaint requirements.

Furthermore, we encourage packagers, labelers, and distributors who receive a product complaint to notify those in a dietary supplement's manufacturing chain about product complaints they receive or they, themselves, generate that may relate to operations outside the packagers', labelers', or distributors' control. For example, a distributor who purchases a dietary supplement in bulk for packaging and labeling may complain about product quality to the dietary supplement manufacturer. The manufacturer who receives the complaint must then take appropriate action to determine whether the complaint involves a possible failure of a dietary supplement to meet any CGMP requirements. Thus, the final rule revises the term ''consumer complaint'' to ''product complaint'' to emphasize that the complaint is about the product regardless of the complaint's source.

(Comment 47) One comment disagrees that ''disintegration time'' and ''tablet size'' are appropriate examples of complaints about product quality specifications.

(Response) We disagree with this comment. Complaints about disintegration time or tablet size could indicate a problem with the production and process control system that may affect the quality of the dietary supplement.

(Comment 48) Some comments disagree with the proposed definition of ''consumer complaint'' because it excluded an adverse event, illness, or injury related to the safety of a particular dietary ingredient. The comments say there should be a consistent approach for handling all complaints, including adverse events. One comment states consumers will not be able to determine whether a product quality issue related to CGMP caused an adverse event. This comment expresses concern that not classifying adverse events as consumer complaints could lead manufacturers to avoid investigating certain adverse events and, therefore, prevent them from determining the appropriate cause and implementing the associated corrective action. The comments stress we should not treat complaints related to CGMP issues differently from other complaints and urged us to classify all adverse events as consumer complaints, whether or not they might have been caused by a particular dietary ingredient.

A few comments state the proposal, which did not specifically address adverse event reporting, but did address the broader category of consumer complaints and would require companies to investigate ''adverse event reports,'' may simply create more confusion and may contradict the overall objective of a comprehensive adverse event reporting system. The comments also state neither the food CGMP regulations nor the 1997 ANPRM defined ''consumer complaints.'' The comments say we should delete this definition and deal with consumer complaints separately as part of the new CFSAN Adverse Event Reporting System (CAERS).

One comment states we should define the term ''serious adverse dietary supplement experience.'' The comment would define a ''serious adverse dietary supplement experience'' as ''any adverse dietary supplement experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse dietary supplement experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse dietary supplement experience and, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.''

(Response) We decline to include in the definition of ''product complaint'' an adverse event related to the safety of a particular dietary ingredient. The final rule establishes CGMP requirements for dietary supplements and does not focus on whether dietary ingredients that manufacturers may use in their dietary supplements are inherently safe. Nevertheless, we encourage firms to investigate all complaints, regardless of whether the complaints relate to CGMP. Furthermore, mandatory reporting to FDA of serious adverse events is now required as a result of the enactment of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), signed into law on December 22, 2006. In any event, consistent with these CGMP requirements, manufacturers must establish limits on contamination, as needed, for all ingredients or any component they use in manufacturing a dietary supplement.

We agree it may be unclear whether a particular product complaint is related to CGMP. Final § 111.560, relating to product complaints, applies in situations where the product complaint involves a ''possible failure of a dietary supplement to meet any of its specifications or any other requirements of this part.'' Thus, if a firm is unclear whether a particular complaint it receives relates to a CGMP issue, we would consider that complaint to be related to a ''possible failure'' to meet CGMP. Consequently, the firm must

comply with the requirements in subpart O, unless the firm affirmatively determines that the complaint is not related to a ''possible failure'' to meet CGMP, and therefore, is not a ''product complaint.'' To make this clear, we revised the definition so that it applies to any ''communication * * * that could be related to good manufacturing practice'' rather than to be any ''communication * * * that is related to good manufacturing practice.''

We disagree with comments that suggested that the requirements for product complaints would somehow contradict the overall objective of the CAERS. This final rule has no effect on the mandatory or voluntary reporting of adverse events. We agree some adverse events may be related to a failure to ensure the quality of the dietary supplement as required by the final rule. To the extent that an adverse event is associated with CGMP, it would be considered a ''product complaint'' under the final rule. The fact that it is considered a product complaint does not mean that such complaint could not be voluntarily reported as an adverse event through CAERS. Such a complaint may be required to be reported under the mandatory reporting requirements of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), signed into law on December 22, 2006. We have added ''illness or injury'' to the final rule's definition of ''product complaint'' as an example of a product problem relating to CGMP to help clarify that there may be some overlap in the type of complaints related to product quality that may also be considered an adverse event.

As for defining ''serious adverse dietary supplement experience,'' we decline to add such a definition to the final rule. We define certain terms in a rule to give those terms a clear and consistent meaning. None of the provisions in this rule addresses or even mentions ''serious adverse dietary supplement experiences,'' so there would be no advantage in codifying a definition for the term in this final rule. If, however, the comment meant to narrow the definition of ''consumer complaint'' to ''serious'' illness, or injury, we decline to do so. If a consumer reports an illness or injury, which he or she attributes to consuming a dietary supplement, the report may indicate a problem with the production and process control system for that dietary supplement, even if the injury or illness is not ''serious'' or severe.

We have, however, decided to delete the last two sentences in the proposed definition of ''consumer complaint'' (now ''product complaint'' in the final rule). These sentences explained, in part, that a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient independent of whether the product is produced under CGMP. We deleted those sentences because they are unnecessary to include in the definition and can be included as further explanation of what the definition of ''product complaint'' means in the preamble discussion.

The proposed definition of ''consumer complaint'' used the phrase ''expressing dissatisfaction with the quality of a dietary * * * supplement;'' the final rule uses the phrase ''expressing concern, for any reason, with the quality of a dietary supplement.'' This change is to ensure that even if the consumer is not actually dissatisfied with the product, but has a concern with the product, this is still handled as a product complaint.

We made several editorial or grammatical changes to the definition of product complaint in this final rule for simplicity and revised the order of the listed examples of product complaints. For example, the proposed definition of ''consumer complaint'' states the term ''means communication that contains any allegation * * *.'' The final rule defines ''product complaint'' as meaning ''any communication that contains any allegation * * *.'' Another nonsubstantive change was to insert the words ''dietary supplements that are'' before ''superpotent, subpotent'' to give the reader a clear understanding as to the article that is superpotent or subpotent.

Finally, we added ''electronic'' as an example of how a product complaint could be communicated to ensure that all forms of communication are included and added ''current'' to modify ''good manufacturing practice'' for consistency.

We discuss in section V of this document, our general response to the comment that stated that neither the food CGMP regulations nor the 1997 ANPRM contains a definition of ''consumer complaint,'' is in our discussion of whether this final rule exceeds our authority or it has to be identical to the food CGMP regulations. More specifically, we acknowledge that the industry draft that we published in the 1997 ANPRM did not define ''consumer complaint.'' The industry draft did contain provisions that would be directed to ''complaint files.'' The provisions for complaint files would require the use of written procedures to handle complaints, retention of records of complaints for a certain time period, and the inclusion of specific information in the record of a complaint.

14. Quality

For purposes solely of this final rule we have decided to define ''quality.'' Quality means that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition and limits on contaminants and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

(Comment 49) Some comments asked that we define ''quality.'' Some comments claimed the proposal described ''quality'' in terms of ''identity,'' ''purity,'' and ''composition.'' One comment would define ''quality'' as ''the total characteristics of a product that bear on its ability to satisfy stated (i.e., labeled) or implied needs of identity, purity, strength and composition.'' Another comment would define ''quality'' as ''having the appropriate identity, purity, and strength for the intended purpose.'' Another comment would define quality using all the other attributes of identity, purity, strength and composition.

(Response) For purposes only of this final rule, we have added a definition of quality. This definition is not intended to apply to CGMP requirements other than those that apply to dietary supplements. In section III of this document, in the overview discussion, we discuss the concept of ''quality'' as it applies to these dietary supplement CGMP requirements and the distinction between the use of the term in the final rule and in the proposed rule.

Because we have defined ''quality'' as encompassing identity, purity, strength, and composition, we have revised each section with requirements for the ''identity, purity, quality, strength, and composition'' to remove the word ''quality.'' The affected sections in this final rule are: § 111.3 (definition of batch); § 111.3 (definition of lot); § 111.65 (''What are the requirements for quality control operations?''); § 111.70 (''What specifications must you establish?''); § 111.75 (''What must you do to determine whether specifications are met?''); § 111.80 (''What representative samples must you collect?''); § 111.95 (''Under this subpart E, what records must you make and keep?''); § 111.105 (''What must quality control personnel do?''); § 111.455 (''What requirements apply to holding components, dietary supplements, packaging, and labels?''); and § 111.515

(''When must a returned dietary supplement be bestroyed, or otherwise suitably disposed of?'').

15. Quality Control

The final rule defines ''quality control'' as ''a planned and systematic operation or procedure for ensuring the quality of a dietary supplement.'' The proposed rule defined ''quality control'' as ''a planned or systematic operation for preventing a dietary ingredient or dietary supplement from being adulterated.''

(Comment 50) One comment suggests revising the definition to use more positive language. Specifically, the comment would define ''quality control'' as ''a planned and systematic operation or procedure for ensuring the quality of dietary supplement products.''

(Response) We agree that the comment's suggested language conveys a positive concept about quality control's role and value and adopt the language in part. The final rule's quality control requirements will help ensure compliance with other CGMP requirements and, therefore, will help ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. We have defined the term ''quality'' in this final rule as including preventing a dietary supplement from being adulterated. Consequently, we revised the definition of ''quality control'' to state that ''quality control'' means a planned and systematic operation or procedure ''for ensuring the quality of a dietary supplement.'' We deleted ''for preventing a dietary ingredient or dietary supplement from being adulterated'' in the proposed definition since the concept of quality includes preventing adulteration.

16. Quality Control Personnel

The final rule defines ''quality control personnel'' as ''any person, persons, or group, within or outside your organization, who you designate to be responsible for your quality control operations.''

(Comment 51) Some comments seem to suggest that the reference in the 2003 CGMP Proposal to a ''quality control unit'' mandates a separate unit or department with responsibility for all quality control operations. One comment explains many companies do not have one quality control unit with oversight of all operations within the facility. This comment states companies commonly have each separate section of an operation perform both its function and its own quality control. A few comments would clarify the definition by indicating that a distinct or separate unit need not perform the quality control function. These comments say the quality control function is best performed by a person or persons qualified by training, education, or experience in the different processing areas.

Many comments say we should consider any individual carrying out a quality control function to be part of the quality control unit for purposes of this rule.

(Response) We agree that the quality control function is best performed by a person or persons qualified by training, education, or experience in relevant areas. To the extent that the comments interpreted the proposed definition as requiring firms to have a separate person or group whose sole function in the company is to perform quality control operations or that the quality control functions are limited to those who are employed within the firm, we disagree. As discussed in the preamble to the proposal, the quality control unit should consist of as many people as necessary to perform the quality control operations (68 FR 12157 at 12252). We have reconsidered the use of the term ''unit.'' In order to clarify that we do not intend to require a separate division or office be created, we instead use the term ''personnel.'' Although we have eliminated references to ''unit,'' we still agree that personnel can be a person, persons, or a group, and as many persons as necessary, who perform the quality control operations. The manufacturer must identify the appropriate person or persons to be responsible for the quality control operations associated with a particular manufacturing operation. For example, the manufacturer may designate one individual as a packaging expert who is responsible for the quality control operations related to packaging, designate a second individual as an expert in deciding whether to accept or reject incoming components, and designate a third individual as an expert in deciding whether in-process specifications are met at certain control points. The definition does not limit the other activities that these designated individuals may perform within the manufacturing operations; thus, for example, the packaging expert who performs the quality control function for packaged dietary supplements could also have responsibilities in the actual packaging operation. Quality control responsibilities and specific activities are distinct and separate from any other responsibilities and specific activities that an employee might perform for any other operation. In addition, the quality control operations may be performed by someone outside the organization (such as a contractor).

To clarify these points and to prevent potential misinterpretation of quality control operations, we revised the definition of ''quality control unit.'' Instead of a unit, quality control personnel who perform quality control operations may be a person, persons, or group and may be ''within or outside of your organization.'' We also added a new § 111.12(b) to require you to identify who is responsible for your quality control operations. Under final § 111.12(b) each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations. Throughout the codified, we use the term ''quality control personnel'' when referring to the performance of specific quality control operations. The term ''quality control personnel'' refers to the person or persons designated to perform the particular quality control operation.

17. Representative Sample

The final rule defines ''representative sample'' as ''a sample that consists of an adequate number of units that are drawn based on rational criteria, such as random sampling, and that are intended to ensure that the sample accurately portrays the material being sampled.'' This definition is similar to the proposed definition of ''representative sample.'' We have added ''an adequate'' before ''number'' to emphasize that the sample must be sufficient for its purpose. We also made nonsubstantive grammatical changes to insert ''that are'' between ''and'' and ''intended.''

(Comment 52) Some comments note the proposed rule would use the terms ''representative sample,'' ''reserve sample,'' and ''representative reserve sample'' but would only define ''representative sample.'' The comments ask us to clarify the distinction, if any, between these terms.

(Response) A ''reserve sample'' is a sample that is to be held or kept for a designated time. It differs from a ''representative sample'' in the sense that a representative sample is not always kept; for example, one might take a representative sample to test product quality, but one would not necessarily keep every tested sample.

To clarify this distinction, the final rule now defines a ''reserve sample'' as ''a representative sample of product that

is held for a designated period of time.'' We also revised the rule to refer solely to a ''reserve sample'' rather than use both ''reserve sample'' and ''representative reserve sample.''

18. Reprocessing

The final rule defines ''reprocessing'' as ''using, in the manufacture of a dietary supplement, clean, uncontaminated components or dietary supplements that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a dietary supplement.'' We modified the definition that, in part, read ''* * * dietary supplements that have been previously removed from manufacturing for reasons other than insanitary conditions'' by removing ''for reasons other than insanitary conditions'' to expand the scope of what may be reprocessed. We explain the reason for the latter change in our response to the following comments. We also changed ''unadulterated'' to ''uncontaminated'' to be consistent with the revisions we have made in other sections, including the definition of quality.

(Comment 53) Some comments ask us to clarify whether components or dietary supplements that have been successfully treated to reduce microbial levels to acceptable levels can be reprocessed. Some comments object to the proposed definition of ''reprocessing'' because it did not include components or dietary supplements removed for insanitary conditions, and several comments object to the restrictions to reprocessing described in proposed §§ 111.35(i)(4)(iii) and 111.50(f), because, they argue, the definition and sections associated with reprocessing would not permit the reprocessing of previously insanitary ingredients even if there are processes available that are safe and effective in removing foreign matter, microorganisms, or chemicals that may have rendered the ingredient ''insanitary.'' One comment would revise the definition as follows: ''Reprocessing means using, in the manufacture of a dietary supplement, clean, unadulterated components * * * or dietary supplements that have been previously removed from manufacturing for reasons other than insanitary conditions or that have been successfully reconditioned so that they are suitable for use.''

(Response) We agree that materials can be treated, subjected to in-process adjustments, or reprocessed when there are suitable processes available, and we revised the definition of ''reprocessing'' to reflect this. However, there must be appropriate oversight of the treatment, in-process adjustments, and reprocessing so the dietary supplement will still meet required specifications. Therefore, we added a conforming requirement to final §§ 111.90(b) and 111.140(b)(3)(vi) to require oversight by quality control personnel for any reprocessing, treatment, or in-process adjustment of a dietary supplement that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a dietary supplement (see sections X and XI of this document).

19. Reserve Sample

The final rule contains a new definition of ''reserve sample.'' ''Reserve sample'' is defined as ''a representative sample of product that is held for a designated period of time.'' We explain our reasons for creating this definition in this section under the definition of ''representative sample.''

20. Sanitize

The final rule defines ''sanitize'' as ''to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.''

The final rule's definition of ''sanitize'' differs from the proposal in that the proposed definition would have specified a reduction of 5 logs or 99.999 percent reduction of ''representative disease microorganisms of public health significance'' and ''other undesirable microorganisms'' and would have specified the use of heat or chemicals. The preamble to the 2003 CGMP Proposal explained that we based the proposed definition of ''sanitize'' on the definition of ''sanitization'' in the ''Food Code'' (which is a model that gives food control authorities a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry) because dietary supplements are often consumed without further processing, similar to foods consumed in retail outlets (68 FR 12157 at 12179). The preamble to the 2003 CGMP Proposal also explained that, to achieve the reduction levels in the proposed definition, one would need to validate control measures to ensure they are both appropriate to their operation and scientifically sound. The preamble explained that in many cases, manufacturers may rely on a written certification from the equipment manufacturer or may obtain a written scientific evaluation of a process, especially in cases where two or more control measures are used to accomplish the 99.999 percent reduction in the target pathogen, to ensure the process is adequate to destroy microorganisms of public health significance or to prevent their growth.

(Comment 54) Many comments object to the proposed text concerning the application of heat or chemicals to a food contact surface to yield a reduction of 5 logs or 99.999 percent of representative disease organisms of public health significance. The comments state the aspect of the proposed definition is overly prescriptive, beyond our legal authority, and would not provide additional public health benefits. Many comments say it is inappropriate to use the definition of sanitization from our Food Code because retail and manufacturing operations are distinct. A few comments assert the process of manufacturing dietary supplements shares more in common with food or drug manufacturing than with retail operations. Most comments recommend that we define ''sanitize'' in the manner that was presented in the 1997 ANPRM and consistent with the current food CGMP definition at § 110.3 so that ''sanitize'' means ''to adequately treat dietary product contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.''

One comment states that consistently validating the effectiveness of the sanitizing procedure is impractical and recommended we state instead that equipment, utensils, etc., should be cleaned and sanitized in a manner that keeps undesirable microorganisms and other adulterants from contaminating all components, ingredients, in-process materials, and finished product. The comment claims that, by this approach, the microbial and analytical test results of product produced on a facility's equipment, coupled with random testing of final rinse water after cleaning and sanitizing equipment and utensils, would provide sufficient and continuous evidence of a proper and effective cleaning and sanitizing plan.

Two comments claim that the proposed definition for sanitize denotes ''validation methodology'' found in drug CGMP, and that we must base dietary supplement CGMP on food rather than on drug standards.

Other comments express concern about validating control measures to ensure that they are scientifically sound and appropriate to operations and the economic burden to do the testing. A few comments state it would be difficult to show a 100,000-fold reduction on an already cleaned surface, particularly if the pre-sanitization level is at or near the lower limit of the test method employed.

One comment states the definition required the manufacturer to demonstrate a 100,000-fold reduction in microbial count every time a food contact surface is sanitized. A few comments express concern that processing lines would have to be closed down each time they are sanitized in order to test them, creating a financial hardship especially on smaller operations. Other comments ask us to give companies the flexibility necessary to monitor sanitation needs based on individual products and manufacturing operations to be consistent with existing industry practices and food and drug CGMPs.

One comment requests we clarify that a sanitizing agent for use on food processing equipment must be approved in accordance with part 178, *Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers* (21 CFR part 178) and our expectations with respect to what documentation would be necessary to prove the effectiveness of the sanitizer used. Two comments say the proposed definition of sanitize means that manufacturers must perform validation studies to demonstrate that the sanitizers they are using reduce the microbial load on equipment by 100,000-fold, a requirement for a ''sanitizer'' under regulations issued by the Environmental Protection Agency. The comments say a sanitizer should not be held to this standard for the purpose of reducing microbial loads on food product contact surfaces, and that manufacturers of a solid dosage form may not need to ''sanitize'' their equipment because the processing environment is not suitable for microbial growth due to the low water activity. One comment recommended using the approach in the Food Code, which specifies conditions under which chemical sanitizers listed in § 178.1010 may be used, including the requirement that they be used in accordance with the Environmental Protection Agency-approved manufacturer's label use instructions, and be used for dietary supplements rather than imposing a validation requirement on manufacturers.

Some comments would divide the definition of ''sanitize'' by creating separate definitions for ''sanitize'' and ''sanitizing agent.'' The comments would define ''sanitize'' as meaning ''to adequately treat equipment, containers, utensils, or any other dietary product contact surface by applying a sanitizing agent on cleaned food contact surfaces.'' One comment would define ''sanitizing agent'' as ''cumulative heat or chemicals that, when evaluated for efficacy, yield a reduction of 5 logs, which is equal to 99.999 percent reduction, of representative disease microorganisms of public health significance and substantially reduce the numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.'' Another comment would define ''sanitizing agent'' in a similar manner, except it would omit references to a 5-log reduction.

(Response) The proposed definition of ''sanitize'' was intended to give firms the flexibility to monitor sanitation needs based on their products and operations. We did not intend to suggest that manufacturers had to demonstrate a 100,000-fold reduction in microbial count every time they sanitized a contact surface, nor did we intend, as some comments claimed, to have firms close down processing lines every time they were sanitized to test them for microbial reduction. Rather, the language of the proposed rule was intended to make it clear that processes used to sanitize contact surfaces should be effective. However, we recognize that the proposed definition caused confusion as to our intent. The proposed definition may have been interpreted as proposing validation to ensure an area was sanitized; however our intent was simply to require that effective sanitizers and sanitizing processes be used, just as in food establishments. Therefore, in order to clarify the provision, we have revised the definition of ''sanitize'' to be consistent with § 110.3(o). The final rule defines ''sanitize'' as adequately treating ''cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.'' The final definition of sanitize does not include any statements about mechanisms that you may use to achieve compliance because including such nonbinding information is inconsistent with our current practices for establishing regulations.

We note that the Environmental Protection Agency has regulatory authority over certain uses of sanitizers as pesticide chemicals and we have regulatory authority over certain uses of sanitizers as food additives. Under section 201(q)(1)(B) of the act, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) and the Antimicrobial Regulation Technical Corrections Act (ARTCA) (Public Law 105–324), certain substances used as food contact surface sanitizing solutions are subject to the Environmental Protection Agency's regulatory authority as pesticide chemicals. The Environmental Protection Agency recently codified tolerance exemptions under section 408 of the act (21 U.S.C. 346a) for those food contact surface sanitizing solutions that were previously subject to our authority at § 178.1010 and transferred to the Environmental Protection Agency's authority under FQPA and ARTCA (see 40 CFR 180.940 (69 FR 23113, April 28, 2004). Such pesticide chemicals must comply with the Pesticide Tolerance regulations in 40 CFR 180.940. Sanitizers used on food packaging must comply with our regulations at § 178.1010. For an in depth discussion of appropriate sanitizers for food contact surface use, see the Environmental Protection Agency's *Pesticides; Tolerance Exemptions for Active and Inert Ingredients for Use in Antimicrobial Formulations (Food Contact Surface Sanitizing Solutions)* (69 FR 23113, April 28, 2004) and *DIS/TSS–4 Efficacy Data Requirements Sanitizing Rinses (for previously cleaned food-contact surfaces)* (January 30, 1979) (Ref. 27) (available on the Internet at *http://www.epa.gov/oppad001/dis_tss_docs/dis-04.htm*).

21. Theoretical Yield

The final rule defines ''theoretical yield'' as ''the quantity that would be produced at any appropriate step of manufacture or packaging of a particular dietary supplement, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.''

We received no substantive comments on the proposed definition.

22. Water Activity

The final rule defines ''water activity'' as ''a measure of the free moisture in a component or dietary supplement and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.''

We received no substantive comments on the proposed definition.

23. We

The final rule explains that ''we'' means the United States Food and Drug Administration.

The final rule's definition is identical to the proposed definition. We received no substantive comments on the proposed definition.

24. You

The final rule defines ''you'' as a ''person who manufactures, packages, labels, or holds dietary supplements.''

25. What Other Terms Did the Comments Want Defined?

(Comment 55) Some comments ask us to define ''adulteration'' (based on the provisions of section 402 of the act), ''dietary ingredient,'' and ''dietary supplement'' (based on the definition in section 201(ff) of the act).

(Response) We decline to revise the rule as suggested by the comments. The terms have meaning within the context of the act and case law. Further, under final § 111.3 the act's definitions and interpretations ''apply to such terms when used in this part.'' Thus, there is no need for us to define the terms as requested by the comments.

(Comment 56) Proposed § 111.35(e)(2) would require a person to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration, and proposed § 111.35(f) would require monitoring of the in-process control points, steps, or stages to ensure these established specifications are met and to detect any unanticipated occurrence that may result in adulteration. Some comments ask us to define the term ''control point'' as ''any point, step or stage in the manufacturing process where control is necessary to prevent adulteration.''

(Response) We decline to add a definition of ''control point'' as requested by the comments. Instead, we revised final § 111.75(b) (formerly proposed § 111.35(f)) to state that you must monitor the in-process points, steps, or stages where control is necessary to ensure the quality of the finished batch of dietary supplement; this revision eliminates the need to define ''control point.''

(Comment 57) Several comments would have us define one or more of the following terms: Identity, purity, strength, and composition. Some comments suggest specific text for the definitions.

Similarly, some comments suggest codifying the preamble description that we used for these terms, i.e., the phrase ''identity, purity, quality, strength, and composition'' means that the production on a batch-by-batch basis is consistent with the master manufacturing record and is what it is represented on the label to be (identity); is without impurities and is the desired product (purity); is the identity, purity, and strength for its intended purpose (quality); is the concentration, that is, the amount per unit of use intended (strength); and is the intended mix of product and product-related substances (composition) (68 FR 12157 at 12176). One comment says ''identity'' should mean ''a substance or product is what it is represented on the label to be.''

One comment says that it does not seem appropriate to define the term ''purity'' to mean ''without impurities.'' The comment states it would be difficult to consider an herbal extract as being ''pure'' because it is a mixture of naturally occurring compounds in a solvent. Another comment suggests the term ''purity'' be defined to mean ''free from objectionable and/or deleterious levels of impurities including, but not limited to, heavy metals, pesticides, mycotoxins, radioactivity, filth, extraneous material, molds, yeasts and bacteria.'' Another comment suggests defining the term ''purity'' as ''having the intended identity and composition and being without significant impurities.'' However, the comment does not explain what is meant by ''without significant impurities.''

One comment suggests defining the term ''strength'' as ''having the intended concentration, that is, the amount of the dietary ingredient per unit of use (tablet, capsule, soft gel, teaspoon, or other unit).'' Another comment expresses concern about the use of the term ''strength'' in relationship to nonstandardized herbals because there are no current industry standards for these products. This comment suggests we clarify the term ''strength'' so it refers to having the correct amount of a stated ingredient. One comment notes St. Johns wort has a composition of approximately 40 different constituents in addition to the essential oil that contains numerous constituents. The comment asks which constituent it should use to determine ''strength.'' Another comment would use the term ''quantity'' instead of ''strength.''

One comment would define ''composition'' as ''having the intended mix of components or ingredients, including dietary ingredients.'' Another comment would delete ''composition'' from the rule because, the comment claimed, an FDA investigator might conclude that ''composition'' refers to every constituent of every botanical. According to this comment, there are many tests that could be used to identify the botanical constituents, but that it would be economically exhausting considering the number of botanical constituents, and it would not contribute to quality or safety.

(Response) We decline to revise the rule to define identity, purity, strength, or composition. The exact way in which the dietary supplement industry uses these terms may vary, and defining these terms could limit the flexibility that is needed to accommodate such variations.

Nevertheless, to elaborate on our interpretation of identity, purity, strength, and composition, and to respond to the particular concerns raised by some comments, we provide the following information.

a. *Identity*. The ''identity'' of a dietary supplement refers to the dietary supplement's consistency with the master manufacturing record and/or that it is the same as described in the master manufacturing record.

b. *Purity*. The ''purity'' of a dietary supplement refers to that portion or percentage of a dietary supplement that represents the intended product. For example, amino acids generally can exist in two forms (i.e., dextro (D-, or right) and levo (L-, or left) forms) called enantiomers. Enantiomers have the same chemical formula and the same chemical structure, but differ in their three-dimensional orientation. If you manufacture a dietary supplement to provide the amino acid L-arginine, and you determine that 90 percent of the manufactured product is L-arginine and 10 percent of the manufactured product is D-arginine, you could describe your L-arginine product as ''90 percent pure.'' As another example, if you manufacture a mixture of triglycerides that provides polyunsaturated fatty acids in the diet, the manufactured triglycerides may contain small amounts of free fatty acids and sterols. The free fatty acids and sterols could derive, for example, from the source of the triglycerides or could be byproducts of the manufacturing process. If you determine that 95 percent of the manufactured product is the mixture of the triglycerides that provides the polyunsaturated fatty acids, and 5 percent of the product is free fatty acids and sterols, you could describe the purity of your product as ''95 percent pure.''

Just as we use the term ''purity'' to refer to the identity and amount of a dietary supplement that is the desired product, we use ''impurity'' to refer to the identity and amount of a dietary supplement that is not the desired product. In the previous examples, we

view the D-arginine that is present in the product that is intended to be L-arginine as an ''impurity,'' and we view the free fatty acids and sterols that are present in the product that is intended to be a mixture of triglycerides that provide polyunsaturated fatty acids in the diet as ''impurities.'' For the purposes of these examples, we do not view these ''impurities'' as ''contaminants.''

If the comments were concerned that the dietary supplement CGMP requirements regarding a dietary supplement's ''purity'' mean that we expect you to characterize each constituent of a natural product to determine whether each constituent is present in a certain pre-established quantity (i.e., purity specification) to determine whether it contributes to the ''purity'' of the dietary supplement or would be considered as an ''impurity,'' we do not consider such constituents to be ''components'' of a dietary supplement (see discussion of the definition of component in this section). For example, if you manufacture a dietary supplement containing fish oil, we would not consider the triglycerides, which are constituents of the fish oil, to be components. Likewise, we would not consider particular fatty acids (such as the polyunsaturated fatty acids docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA)), which are constituents of the triglycerides, to be components of the dietary supplement. In this example, you would be required to establish a purity specification for the amount of triglycerides in the fish oil. (Note that if you are manufacturing fish oil to provide the fatty acids DHA and EPA in the dietary supplement, the component specifications for the fish oil must include a strength specification for DHA and EPA in whatever amount you determine is necessary to meet the specification for strength of DHA and EPA in the dietary supplement.) We do, however, expect you to set appropriate limits on contaminants (e.g., toxic substances) that are known to be constituents of botanical extracts or other natural products that are likely or certain to contain constituents that are harmful.

c. *Strength*. The strength of a dietary supplement relates to its concentration. By concentration, we mean the quantitative amount per serving (for example, weight/weight, weight/volume, or volume/volume). Therefore, for purposes of this final rule, strength does not refer simply to the quantity of an ingredient, rather it refers to the amount of a stated ingredient per a specified unit of measure.

If the comments were concerned that the ''strength'' of a dietary supplement meant that you need to establish the quantitative amount per unit of measure of each constituent in a dietary ingredient, such as a botanical extract or natural product, we do not consider such constituents to be ''components'' of a dietary supplement, unless you add such constituents as components (as in an extract) (see discussion of the definition of component in this section).

We do not consider the rule's requirements on dietary supplement strength as necessarily relating to the individual constituents of such products. Whether the requirements regarding dietary supplement strength apply to one or more constituents of dietary ingredients in a dietary supplement depends on what you are manufacturing. For example, if you are manufacturing vitamin C, and your source of vitamin C is rosehips, you would establish a strength specification for vitamin C in the finished batch of the dietary supplement (e.g., ''x milligrams (mg) of vitamin C per tablet''). You are required to ensure that the dietary supplement does in fact contain ''x mg of vitamin C per tablet.'' Alternatively, if you are manufacturing rosehips and not vitamin C from rosehips, the strength specification that you establish for the finished batch of the dietary supplement is the strength of the rosehips themselves (i.e., the concentration of rosehips in the final product, such as ''x mg of rosehips per tablet''). You are required to ensure that the product does in fact contain ''x mg of rosehips per tablet.''

We discuss the requirements to establish and meet specifications in our discussion of subpart E (see section X of this document).

d. *Composition*. A dietary supplement's ''composition'' refers to the specified mix of product and product-related substances in a dietary supplement. For example, a dietary supplement manufactured to provide vitamin C may contain, in addition to vitamin C, a tablet coating agent and substances used as binders. The composition could be described as the percent of the dietary supplement that is vitamin C, the tablet-coating agent, and each binder.

e. *Other terms*.

(Comment 58) Several comments would revise the rule to define ''manufacturer.'' Many comments ask whether the rule applies to certain types of companies or professionals and said a definition of ''manufacturer'' would clarify the rule's applicability.

Some comments suggest specific text for a definition. For example, one comment would define ''manufacturer'' as ''a person who formulates or changes the composition or physical characteristics of a dietary supplement or who packages or labels the product in a container for distribution'' to clarify that a company that does not manufacture a specific dietary supplement, but purchases a dietary supplement in bulk and then packages or labels the bulk dietary supplement for sale to consumers, is still subject to dietary supplement CGMP requirements. The comment cites our proposed definition of ''manufacturer'' in our infant formula CGMP proposal (see 61 FR 36154 at 36209, July 9, 1996 (proposing to define a ''manufacturer'' as ''a person who prepares, re-constitutes or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution'')).

Other comments would define ''manufacturer'' to exclude a health care practitioner or herbalist and noted the Canadian Natural Health Product regulations do not apply to health care practitioners.

(Response) We decline to define ''manufacturer'' in the final rule. In section III, footnote 1 of this document, we explain that ''manufacture'' is a broad term and is not limited to production, packaging, or labeling activities. Consequently, we prefer to explain our interpretation of the final rule in this preamble and to have the codified provisions state general principles rather than attempt to capture subtleties in a definition of ''manufacturer.''

(Comment 59) Proposed § 111.35(e)(1) through (e)(3) would require you to establish specifications for identity, purity, quality, strength, and composition at receipt, in-process, and finished batch stages, while proposed § 111.35(g)(1) would require you to test each dietary supplement at the finished batch stage before release for distribution to confirm that specifications are met, provided that there are scientifically valid analytical methods available to perform such testing. If your quality control unit determined that finished batch testing could not be completed for any specification because a scientifically valid analytical method was not available, proposed § 111.35(g)(2) and (g)(3) would require you to perform testing on components and at the in-process stage to determine whether that specification is met. The preamble to the 2003 CGMP Proposal explained that a scientifically valid analytical method is one that is based on scientific data or

results published in, for example, scientific journals, references, text books, or proprietary research (68 FR 12157 at 12198).

Several comments agree that scientifically valid analytical methods are those that are based on scientific data or results published in scientific journals, references, textbooks, or proprietary research. However, several comments ask us to define or better explain the terms ''test'' or ''scientifically valid analytical method'' as used in the dietary supplement CGMP final rule. One comment argues that, because of the evolving nature of methodology for ingredients used in dietary supplements, we should give the industry more guidance as to what can be considered authoritative for the purpose of compliance with CGMP. Some comments state we should acknowledge methods from the Institute for Nutraceutical Advancement (INA), American Herbal Pharmacopoeia (AHP), European Pharmacopoeia, and the World Health Organization (WHO) as scientifically valid analytical methods. One comment notes the USP establishes scientifically valid procedures in its compendia and encouraged us to designate compendial procedures as ''scientifically valid'' by defining ''scientifically valid'' to include compendial procedures. The comment further argues that failure to acknowledge compendial procedures as scientifically valid would be inconsistent with section 403(s)(2)(D) of the act, which acknowledges the role of compendia, by considering a dietary supplement misbranded if the supplement is covered by the specifications of an official compendium, is represented as conforming to the specifications of an official compendium, and fails to so conform.

Other comments would define ''validation'' and ''verification'' and directed us to ''ANSI Standard A8402–1994'' (a description of validation and verification standards).

(Response) We decline to define ''test,'' ''scientifically valid analytical method,'' or ''scientifically valid method'' in this final rule. As the comments recognized, the analytical methods for components are evolving. A regulatory definition for ''test,'' ''scientifically valid analytical method,'' or ''scientifically valid method'' could become obsolete if we based it on specific sources such as INA, AHP, or USP that may or may not themselves stay current or that may be modified in a manner that did not enjoy widespread support.

The preamble to the 2003 CGMP Proposal acknowledged that compendia can have a role in establishing tests used to determine whether specifications are met. For example, we noted that compendial standards may be appropriate reference materials for use in conducting tests or examinations (68 FR 12157 at 12208). However, we did not list specific compendia that would be suitable sources or scientifically valid analytical tests, and are not listing such compendia in this final rule. The compendia identified in the comments, i.e., INA, ANSI, AHP, and USP, may include some methods that are based on scientific data or results published in scientific journals, references, textbooks, or proprietary research, but also contain some methods that are not based on such data or results. Thus, whether or not a method is scientifically valid is not determined solely by its inclusion in a compendium. Rather, it is the responsibility of quality control personnel to approve the use of those scientifically valid tests that will ensure a product's identity, purity, strength, and composition whether or not such tests are contained in a particular compendium.

We also decline to define ''validation'' and ''verification'' because the final rule does not establish any requirements that use these terms.

(Comment 60) One comment asks us to define the terms ''adequate,'' ''sufficient,'' and ''qualified'' and argues that, without these definitions, an FDA investigator may assert that something or someone is not adequate, sufficient, or qualified.

(Response) We decline to define ''adequate,'' ''sufficient,'' or ''qualified'' in this final rule. Deciding what is ''adequate'' or ''sufficient,'' or who is ''qualified'' must be done on a case-by-case basis, depending on the operations and the particular facts. As explained in section V of this document, we do not need to, nor could we, predict with mathematical precision how many inches or feet, for example, would be ''adequate space'' to allow for cleaning a particular piece of equipment that could be applied to every size of facility and every operation. Furthermore, defining ''adequate,'' as defined in part 110, as ''that which is needed to accomplish the intended purpose in keeping with good public health practice'' would still require context to determine whether, in a particular operation and based on a particular set of facts the particular practice was ''adequate.'' Moreover, for terms such as ''adequate,'' ''sufficient,'' and ''qualified,'' where there has been common usage in the food industry to enable manufacturers and FDA investigators to comprehend and apply such terms to a particular operation, we do not believe a definition for these terms is necessary.

(Comment 61) Several comments would define the terms ''certificate of analysis,'' ''certificate of compliance/conformance,'' and ''continuing product guarantee.'' Most comments include these terms in a list of terms that they want us to define to ensure consistent interpretation of the rule throughout the industry. One comment says a standard for documentation, such as a certificate of analysis, would put greater emphasis on the firm's responsibility to comply with CGMP.

(Response) We decline to define these terms as suggested by the comments. We have included, in the codified, the use of a certificate of analysis as an option to determine whether certain specifications have been met. The final § 111.75(a)(2)(ii)(B) requires that certain information be provided in a ''certificate of analysis.'' This provision states that the certificate of analysis must include a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations, provided you satisfy certain other criteria.

As for the claim that a standard for documentation, such as a certificate of analysis, would emphasize a firm's responsibility to comply with CGMP, we encourage firms who are excepted from the scope of the rule in final § 111.1 and who supply dietary ingredients and other components to follow dietary supplement CGMP requirements.

We decline to define ''certificate of compliance/conformance'' or ''continuing product guarantee'' because the final rule does not establish any requirements that use these terms.

26. What Definitions Did the Comments Want Us to Delete?

(Comment 62) Some comments would delete certain definitions (e.g., ''component'' and ''ingredient'') because these terms do not appear in the food CGMP, the 1997 ANPRM, or both.

(Response) We decline to delete any definition for the reasons stated by the comments. As discussed in section V of this document, Congress did not require dietary supplement CGMP requirements to be identical to the food CGMP requirements, so the mere fact that a definition may not appear in a food CGMP regulation does not mean we must delete that definition from this final rule, especially when the comments offered no other justification for deleting the definition. Definitions

provide clarity and consistency in interpreting various terms in a rule.

D. Do Other Statutory Provisions and Regulations Apply? (Final § 111.5)

Final § 111.5 states: ''In addition to this part, you must comply with other applicable statutory provisions and regulations under the act related to dietary supplements.'' Proposed § 111.5 stated that, in addition to the dietary supplement CGMP requirements, ''you must comply with other applicable statutory provisions and regulations under the act related to the manufacturing, packaging or holding of dietary ingredients or dietary supplements.''

Section 111.5 reminds you that other statutory or regulatory requirements, not included in the dietary supplement CGMP requirements, may apply to your particular products, operations, or activities. In our further review of this provision, we determined that we do not need to elaborate on the individual operations and have shortened the provision to eliminate the references to particular operations. You are required to comply with other applicable statutory and regulatory requirements, and we have retained this provision to ensure you understand that this final rule does not relieve you of your responsibilities to comply with other applicable statutory and regulatory requirements related to dietary supplements.

E. What Sections Did We Remove From the Rule, and Why?

The final rule omits sections that were in the proposed rule. Proposed § 111.2, ''What Are These Regulations Intended to Accomplish,'' would have described the rule's purpose as establishing the minimum CGMP you must use to the extent that you manufacture, package, or hold a dietary supplement. Proposed § 111.6, ''Exclusions,'' would have excluded ''persons engaged solely in activities related to the harvesting, storage, or distribution of raw agricultural commodities that will be incorporated into a dietary supplement by other persons'' from the dietary supplement CGMP requirements.

1. ''What Are These Regulations Intended to Accomplish?'' (Proposed § 111.2)

We elected to remove proposed § 111.2 from the final rule because we realized that it created no enforceable obligations and provided little, if any, helpful information. The few comments that address proposed § 111.2 either disagreed with its general statement or sought to weaken the provision; the comments' arguments prompted us to reconsider whether proposed § 111.2 was necessary at all, and, in the end, we decided to delete the proposed section. We describe the comments on proposed § 111.2 in the following paragraphs.

(Comment 63) Several comments argue the proposed rule went beyond the ''minimum standards'' mentioned in proposed § 111.2. These comments also assert the proposed rule lacked flexibility.

(Response) We disagree with the comments. In several instances, the proposed requirement is practically identical to requirements in the umbrella food CGMP regulations. For example, most of the proposed requirements for personnel, physical plants, and equipment and utensils correspond to long-established, similar requirements in the umbrella food CGMP regulations in part 110. In other instances, the proposed rule would require a particular action or result (such as establishing specifications for components, in-process controls, manufactured dietary supplements, and packaged and labeled dietary supplements under proposed § 111.35(e)), but gave firms the flexibility and the responsibility to decide what those specifications will be. We have included flexibility where it is appropriate to do so, and, after we revised parts of the rule in response to the comments, the final rule provides more flexibility than the proposal. For example, final § 111.75 sets forth criteria for relying on a certificate of analysis to ensure that certain specifications for components are met and for when you can test a subset of finished batches for a select number of specifications; this differs considerably from the proposal which would have required testing all batches for all specifications.

(Comment 64) One comment would revise proposed § 111.2 to read as follows: ''These regulations recommend general minimum current good manufacturing practices that, when modified by manufacturer product specifications, will extend to the manufacture, package, or holding of dietary ingredients or dietary supplements for that manufacturer.''

(Response) We decline to revise the rule as suggested by the comment. Section 402(g) of the act states that ''The Secretary may by regulation prescribe good manufacturing practices for dietary supplements.'' If a dietary supplement has been prepared, packaged, labeled, or held under conditions that do not meet the final rule's requirements, the dietary supplement is deemed to be adulterated under section 402(g)(1) of the act. Here, the comment's suggestion that dietary supplement CGMP requirements could be ''modified by manufacturer product specifications'' would create uncertainty over whether manufacturers could unilaterally ''modify'' their product specifications to fit a batch that failed to meet specifications or claim that a violation was ''cured'' by a manufacturer's new product specification. In any event, given that we decided to omit proposed § 111.2 altogether, the change sought by the comment is moot.

2. ''Exclusions'' (Proposed § 111.6)

As we stated earlier in this section, proposed § 111.6 would exclude from the dietary supplement CGMP requirements persons who engage solely in activities related to the harvesting, storage, or distribution of raw agricultural commodities that would be incorporated into a dietary supplement by other persons. However, as we explained in our response to comment 27 of this document, we decided that the exclusion was not necessary, given the changes that we made to final § 111.1(a).

Nevertheless, we received several comments on proposed § 111.6, and we address those comments here.

(Comment 65) One comment would revise the rule to exclude or use different requirements for small businesses. The comment suggested we categorize small businesses by employment levels or dollar sales and adopt a tiered enforcement strategy similar that used in other government programs, such as those under the Occupational Safety and Health Act, the Americans with Disabilities Act, and the Family Leave Act. Another comment would exempt small businesses from the specific requirements for testing if those businesses produce annual batch runs of 25,000 capsules and tablets.

(Response) We decline to exclude small businesses from the final rule or to have different criteria for such businesses. As we stated in our response to comments 1, 3, and 16, there is no reason to assume that Congress meant to apply different or lesser CGMP requirements, or no CGMP requirements at all, to dietary supplements made by small businesses. Dietary supplement CGMP requirements help to ensure the quality of the dietary supplement and, among other things, that a dietary supplement meets its specifications, that it contains the ingredients specified in its master manufacturing record, and that it is not contaminated. Consumers should be able to expect that the dietary supplements they purchase meet CGMP requirements regardless of the manufacturer's size. However, to help

businesses comply with dietary supplement CGMPs, we are giving businesses with fewer than 500 employees but 20 or more employees a compliance date of 24 months after the date of publication of this final rule, and we are giving businesses with fewer than 20 employees a compliance date of 36 months after the date of publication of this final rule.

We carefully considered the size of a business when developing these regulations. The most common Small Business Association size standard applicable to manufacturers covered by this final rule is 500 employees. Based on comments and our knowledge of the dietary supplement industry, we know that there are a number of dietary supplement manufacturers who fall significantly below the standard of 500 employees. To accommodate these manufacturers, we have established different compliance dates as noted.

(Comment 66) One comment would exempt ''consolidators'' (whom it described as individuals who purchase raw agricultural commodities for sale to raw ingredient manufacturers) from the rule. Some comments suggest expanding the exclusion pertaining to harvesting, storage, and distribution of raw agricultural commodities to include other common and basic raw botanical processing activities, such as drying, chopping, cutting, size reduction, sifting, grinding, and storage. One comment would delete the word ''solely'' to make the rule more flexible and make it possible to exclude producers, who do not manufacture a distinct product, from the CGMP rule. Another comment expresses concern about potential safety issues that can arise from the early stages of manufacturing, such as the use of improper handling of agricultural commodities and the risk of adulteration; the comment says businesses involved in producing or distributing raw agricultural commodities should be subject to some requirements under the rule. A few comments ask us to draft guidance documents to address activities such as wildcrafting, plant identification, good agricultural practices, and good hygienic practices for wildcrafters (persons who harvest plants grown in the wild), and growers and brokers and specific service providers (millers, extractors). Some comments would exempt individual wildcrafters because wildcrafters deal in relatively small amounts of material at a time and sell their material to larger brokers who combine materials from different pickers together.

(Response) As explained in our responses to comments 29 and 30, persons who only manufacture or supply a component that will be further processed as a dietary supplement by another person are not within the scope of this final rule. Thus, a ''consolidator'' who simply buys raw agricultural commodities and then sells them to dietary ingredient manufacturers would not be subject to this final rule. Similarly, persons engaged in drying, chopping, cutting, size reduction, sifting, and grinding of raw agricultural commodities which they then sell to others for processing into a dietary supplement would not be subject to this final rule. We note, however, that such persons are not exempt from other regulatory requirements. We remind readers that a dietary ingredient is a food under section 201(f)(3) of the act. Consequently, a raw agricultural commodity that is a dietary ingredient is still subject to the umbrella food CGMP requirements in part 110, and activities such as drying, chopping, and cutting are what we have long considered to be types of food processing.

As for ''wildcrafters,'' if they package and label raw agricultural commodities as dietary supplements or sell them to consumers for use as a dietary supplement, we would consider them to be manufacturers of a dietary supplement and subject to the rule. If, however, the wildcrafter simply sells the raw agricultural commodity to another for incorporation into a dietary supplement, it would not be subject to this final rule, but might be subject to the CGMP requirements in part 110. Persons engaged in the harvesting, storage, or distribution of raw agricultural commodities, whether for distribution as a dietary supplement or for distribution as a dietary ingredient to a dietary supplement manufacturer, may want to read our guidance entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' available at *http://www.cfsan.fda.gov/~dms/prodguid.html* (Ref. 28). This guidance addresses common areas of food safety concern in the growing, harvesting, sorting, packing, and distribution of fresh produce, and contains principles that would apply to raw agricultural commodities, such as herbs and botanicals.

As for the comment that would delete the word ''solely'' from proposed § 111.6, we note that such a change is no longer necessary since we are deleting § 111.6. However, we caution that only those persons or entities that manufacture or supply components that will be further processed as a dietary supplement by others are not subject to the final rule. If you manufacture and sell dietary supplements, in addition to supplying components to others, you would be subject to this final rule under § 111.1(a).

As for potential safety issues arising from the early stages of manufacturing, such as the use of improper handling of agricultural commodities and the risk of adulteration, the final rule, at § 111.75, describes criteria that enable a manufacturer of a dietary supplement to rely on a certificate of analysis. One criterion is that the manufacturer must first qualify the firm providing the component by establishing the reliability of the firm's certificate of analysis through confirmation of the results of the firm's tests or examinations. Firms that improperly handle raw agricultural commodities, such that the commodities that they provide are adulterated, are not likely to be qualified as suppliers of those commodities.

In the future, we will consider the requests to develop guidance for subsets of agricultural and post-harvest activities (such as for hygienic practice for wildcrafters, identifying botanicals) associated with dietary supplement manufacturing, along with other guidance we may find useful as they relate to certain CGMP requirements for dietary supplements.

VII. Comments on Personnel (Final Subpart B)

A. Organization of Final Subpart B

Proposed subpart B contained three provisions regarding personnel. Table 3 of this document lists the sections in final subpart B and identifies the proposed sections that form the basis of the final rule.

TABLE 3.—DERIVATION OF SECTIONS IN FINAL SUBPART B

Final Rule	2003 CGMP Proposal
§ 111.8 What are the requirements under this subpart B for written procedures?	N/A
§ 111.10 What requirements apply for preventing microbial contamination from sick or infected personnel and for hygienic practices?	§ 111.10

TABLE 3.—DERIVATION OF SECTIONS IN FINAL SUBPART B—Continued

Final Rule	2003 CGMP Proposal
§ 111.12 What personnel qualification requirements apply?	§ 111.12
§ 111.13 What supervisor requirements apply?	§ 111.13
§ 111.14 Under this subpart B, what records must you make and keep?	N/A

B. Highlights of Changes to the Proposed Requirements for Personnel

1. Revisions

The final provisions in subpart B include revisions that clarify that the final rule applies only to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.

The final provisions also include revisions that clarify the applicability of the rule to persons who perform labeling operations for dietary supplements.

2. Changes After Considering Comments

The final rule:

- Requires you to establish and follow written procedures to fulfill the requirements of subpart B;
- Provides flexibility regarding the requirement to exclude personnel who might be a source of microbial contamination (e.g., due to illness or open lesions) so that such personnel must be excluded only from operations where such contamination may occur;
- Clarifies that the qualification of personnel and supervisors may be done through education, training, or experience;
- Sets forth a new requirement that you identify qualified personnel to perform quality control operations and requires that such personnel have distinct and separate responsibilities related to performing quality control operations from those responsibilities that the person otherwise has when not performing quality control operations; and
- Sets forth a new requirement to make and keep records that document training of personnel.

C. General Comments on Proposed Subpart B

(Comment 67) Some comments assert one or more proposed requirements are unconstitutionally vague under the Fifth Amendment and arbitrary and capricious under section 706(2)(B) of the Administrative Procedure Act (APA) and therefore should be deleted. The comments focus on:

- Proposed § 111.12(a) which would require ''qualified employees'' and
- Proposed § 111.13(a) which would require ''qualified personnel to supervise.''

In general, these comments say the proposal's failure to define the term ''qualified'' means that persons who are subject to the rule could not discern the meaning of the term. These comments also say the proposal imposes no limits on enforcement officers as to what would satisfy the requirements and, thus would represent an exercise of unbridled discretion and disparate decisionmaking. These comments argue proposed § 111.12(b), which would require employees to have ''the training and experience to perform the person's duties,'' and proposed § 111.13(b), which would require supervisors to be ''qualified by training and experience to supervise,'' would suffice.

(Response) We are not deleting §§ 111.12(a) and 111.13(a) as requested by these comments. As discussed in section V of this document, we disagree that the terms in question are unconstitutionally vague, need to be defined, or may result in discriminatory enforcement. There has been sufficient common usage of these terms in the food industry to enable manufacturers, and those who enforce the requirements, to comprehend and apply such terms ''with a reasonable degree of certainty'' to their particular operations (see *Boyce Motor Lines* v. *United States* 342 U.S. at 340). Further, agencies are permitted to use qualifying terms to enable them to address a wide variety of conditions at companies. For these reasons, we have retained the use of the terms in the final rule. The provisions at issue also give firms the flexibility to determine how to comply with the regulations. We also explain in section V of this document that the final rule does not violate the APA.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.8)

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV. We also respond to individual comments on specific provisions in the same section. Final § 111.8 requires you to establish and follow written procedures to fulfill the requirements of subpart B. Additionally, to ensure that we can evaluate firms' compliance with their written procedures, final § 111.14 requires that a person who manufactures, packages, labels, or holds dietary supplements make and keep records of such procedures. Such records would be available to us under subpart P.

E. What Requirements Apply for Preventing Microbial Contamination From Sick or Infected Personnel and for Hygienic Practices? (Final § 111.10)

The title of this provision has been changed from proposed § 111.10 to clarify that the requirements are related to the prevention of microbial contamination due to the health condition of personnel and not other sources.

1. Final § 111.10(a)

Final § 111.10(a) requires you to take measures to exclude from any operations any person who might be a source of microbial contamination, due to a health condition, where such contamination may occur, of any material including components, dietary supplements, and contact surfaces used in the manufacture, packaging, labeling, or holding of a dietary supplement. This provision is similar to proposed § 111.10. We added ''due to a health condition'' for clarity.

(Comment 68) Several comments suggest that employees who are sick should be allowed to work in areas where they will not come into contact with components, dietary supplements, or contact surfaces, and that the requirements of proposed § 111.10 are too strict. These comments say proposed § 111.10(a) is too broad in stating that such persons be excluded ''from working in any operation.'' These comments explain that such persons may be suitable for performing other tasks, such as warehouse functions or administrative work. These comments would revise proposed § 111.10(a) so that it is acceptable for such persons to work so long as they will not be a vessel for microbial contamination.

Other comments agree with proposed § 111.10(a), and state that employees who are sick should be excluded from the plant, even from areas where products are not processed. These comments state excluding such personnel should be mandatory as the microbes from an open sore, wound, or other source of contamination could contaminate the surrounding air, personnel, etc. For example, if the production area is a closed loop air handling system, then contamination could spread to the other areas through the common air handling units/ducts.

(Response) We agree that some tasks may be suitable for a person who might be a source of microbial contamination. Certain warehouse functions or administrative tasks may be appropriate for such a person to do, provided that these functions or tasks do not expose components, dietary supplements, or contact surfaces to microbial contamination from the person, and provided that the person would not infect others who would then expose components, dietary supplements, or contact surfaces to microbial contamination.

A requirement to exclude employees from being present at work would limit potential microbial contamination, which is the basis of the point made by some comments that employees who are sick should be excluded from the plant. However, the comments do not persuade us to deny firms the flexibility to determine whether it would be appropriate for an employee who may be a source of microbial contamination to work in some areas of the physical plant that are sufficiently separated from areas where product contamination could occur. When considering whether an employee may be permitted to work and whether he/she represents a potential source of microbial contamination, one should look beyond the obvious potential sources of contamination, and consider possibilities such as the forms of indirect contamination discussed by the comments. Therefore, we are revising proposed § 111.10(a) to require you to take measures to exclude ''from any operations any person who might be a source of microbial contamination, due to a health condition, where such contamination may occur, of any material including components, dietary supplements, and contact surfaces used in the manufacture, packaging, labeling, or holding of a dietary supplement.''

As one measure to reduce potential microbial contamination, final § 111.10(a)(1) requires you to exclude, from working in any operations that may result in contamination, any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have an illness, infection, open lesion, or any other abnormal source of microbial contamination, that may result in microbial contamination of components, dietary supplements, or contact surfaces, until the health condition no longer exists. Final § 111.10(a)(1) is similar to proposed § 111.10(a)(1). We have added that the person can acknowledge that he or she may be a source of microbial contamination. We are moving and modifying the prepositional phrase concerning ''working in any operation.'' We also have added the word ''infection'' to clarify the sources of potential abnormal contamination.

(Comment 69) Several comments suggest employees who may be the source of microbial contamination should be permitted to work in areas of the plant where they pose no risk of contamination, and therefore should not be excluded unless they pose such a risk.

(Response) We agree with the comments and are revising proposed § 111.10(a)(1) accordingly. Therefore, you may allow persons with certain health conditions to work in areas of a plant where they pose no risk of contamination even though they must be excluded from other areas where they would pose such a risk.

Final § 111.10(a)(2) requires you to instruct your employees to notify their supervisor(s) if they have, or if there is a reasonable possibility that they have, a health condition stated in § 111.10(a)(1) that could contaminate any components, dietary supplements, or any contact surface.

We did not receive comments specific to proposed § 111.10(a)(2).

2. Final § 111.10(b)

Final § 111.10(b) requires, if you work in an operation during which adulteration of the component, dietary supplement, or contact surface may occur, you to use hygienic practices to the extent necessary to protect against contamination of components, dietary supplements, or contact surfaces. Final § 111.10(b) lists nine hygienic practices, such as wearing outer garments in a manner that protects against contamination, washing hands thoroughly, and wearing, where appropriate, hair nets, caps, beard covers, or other effective hair restraints.

We did not receive any comments concerning proposed § 111.10(b)(1) (wearing outer garments in a manner that protects against contamination), § 111.10(b)(2) (maintaining adequate personal cleanliness), § 111.10(b)(3) (washing hands thoroughly), § 111.10(b)(4) (removing all unsecured jewelry and other objects that might fall into components, dietary supplements, equipment, or packaging and removing hand jewelry that cannot be adequately sanitized), § 111.10(b)(6) (wearing, where appropriate, hair nets, caps, beard covers, and other effective hair restraints), § 111.10(b)(7) (not storing clothing or other personal belongings where components, dietary supplements, or contact surfaces are exposed or where contact surfaces are washed), and § 111.10(b)(9) (taking any other precautions necessary to protect against contamination).

Proposed § 111.10(b)(5) would require the hygienic practices that you use to include maintaining gloves used in handling components, dietary ingredients, or dietary supplements in an intact, clean, and sanitary condition and ensuring that gloves be of an impermeable material.

(Comment 70) One comment asks us to clarify the requirements for the use of gloves in proposed § 111.10(b)(5). The comment says there are situations in which gloves are ineffective or cumbersome. The comment provides as an example, if a person is packaging a bulk material in fiber packs with metal ring lids, bulky gloves can interfere with the finer work such as attaching security tabs, and thin, flexible gloves can be easily damaged by the sharp edges of the metal rings on the lid.

(Response) Final § 111.10(b)(5) requires you to maintain gloves in an intact, clean, and sanitary condition; it does not require you to use gloves in any specific situation. Although there is no requirement for wearing gloves while performing specific operations, you must wear gloves when they are necessary to protect against contamination of any components, dietary supplements, or contact surfaces.

(Comment 71) Proposed § 111.10(b)(8) would require that the hygienic practices that you use, to the extent necessary to protect against contamination, include not eating food, chewing gum, drinking beverages, or using tobacco products in areas where components, dietary ingredients, dietary supplements, or any contact surfaces are exposed, or where contact surfaces are washed.

One comment would substitute the word ''processed'' for the word ''exposed'' in proposed § 111.10(b)(8). The comment says, although areas where components, dietary supplements, and contact surfaces are exposed pose the greatest risk, adulteration is also possible where these items are held (i.e., stored in containers and, thus, not exposed). Furthermore, the comment explains the use of the word ''processed,'' rather than ''exposed,'' would cover all areas intended to be covered by CGMPs and would alleviate the need to specify that the requirement applies to areas where contact surfaces are washed.

(Response) We decline to revise the rule as suggested by the comment. We believe the word ''exposed'' covers all areas intended to be covered by the

requirement, including areas where contact surfaces are washed. We consider an area where contact surfaces are washed to ''expose'' the contact surface. To avoid any confusion, we are modifying § 111.10(b)(8) to say ''* * * any contact surfaces are exposed, or where contact surfaces are washed.'' As written, the requirement to not eat, chew gum, drink, or use tobacco products in areas where components, dietary supplements, and contact surfaces are exposed gives firms appropriate flexibility to determine areas where employees may or may not eat, chew gum, drink, or use tobacco products.

F. What Personnel Qualification Requirements Apply? (Final § 111.12)

Final § 111.12(a) requires you to have qualified employees who manufacture, package, label, or hold dietary supplements. Final § 111.12(a) is similar to proposed § 111.12(a), except that the final rule includes an editorial change to clarify that the requirement is to have the qualified employees do the work rather than merely to have qualified employees.

(Comment 72) The 2003 CGMP Proposal invited comment on whether there is a minimum number of employees needed to manufacture dietary supplements (68 FR 12157 at 12183). Several comments state the final rule should not include such a minimum number because firms should be able to decide for themselves how many qualified personnel they need.

(Response) The final rule does not stipulate a minimum number of employees. However, there should be enough employees to manufacture, package, label, and hold dietary supplements to ensure compliance with the final rule. In general, CGMP suggests the need for a minimum of two persons: One to perform the work, and a second to check the work performed to ensure that a manufacturing deviation or an unanticipated occurrence is not overlooked.

(Comment 73) Some comments about the proposed definition of ''quality control unit'' say the quality control function need not be performed by a distinct or separate unit. These comments say the quality control function is best performed by a person or persons qualified by training, education, or experience in the different processing areas.

(Response) As discussed, we have revised the proposed definition and substituted the term ''personnel'' for ''unit.'' (For the definition of quality control personnel, see section VI of this document.) We agree the quality control functions do not need to be performed by a distinct or separate unit or person and that a person who is qualified by training, education, or experience can serve a quality control function. Therefore, we are adding a new § 111.12(b) to clarify that you must identify who is responsible for quality control operations. Under final § 111.12(b) each person identified must be qualified to perform such operations, and must have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations. The quality control personnel can have dual functions within the facility but should separately perform the different responsibilities.

Final § 111.12(c) requires that each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, have the education, training, or experience to perform the person's assigned functions. Final § 111.12(c) includes a revision associated with final § 111.12(b) by including persons who perform quality control operations as persons who also need to have the education, training, or experience for the assigned functions.

(Comment 74) Several comments state we should revise the rule to allow for any combination of ''training or experience.'' These comments explain it is not always possible for an employee to have both ''training and experience.'' These comments would revise proposed § 111.12(b) to read, ''each person engaged in the manufacture of a dietary product should have the proper education, training, and experience (or any combination thereof) needed to perform the assigned functions. Training should be in the particular operations(s) that the employee performs as they relate to the employee's functions.'' Another comment asks for guidance as to what type of education, training, or experience is required for an employee to be considered qualified.

(Response) We agree with the point made by the comments. We acknowledge that some positions will require an appropriate educational background in addition to any on-the-job training. In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12183) we noted ''training'' may be considered a form of ''education'' and elected to require that employees be qualified by ''training and experience'' rather than ''education, training, and experience.'' The 2003 CGMP Proposal used the conjunction ''and'' because we considered ''experience'' to be different from training, in that ''experience'' is knowledge that a person gains over time, e.g., as he or she becomes increasingly familiar with a particular action or piece of equipment.

These comments persuade us that the rule would be clearer if we added ''education'' to the list of attributes that are used to qualify an employee. We also agree there are some employees who could be qualified based solely on their education or experience and other employees who would become qualified through, for example, on-the-job training before they are left on their own to perform their assigned duties. Rather than revise the rule to list all three attributes and then explain that an employee can be qualified by any combination of the attributes, we have changed the conjunction from ''and'' to ''or.'' Additionally, on our own initiative, we have replaced ''person's duties'' with ''person's assigned functions.'' This change reinforces the principle that the employee's training relates to the functions that he or she is assigned to perform.

We will consider whether it would be useful to provide guidance on what type of education, training, or experience would be sufficient for an employee to be properly qualified. We believe that such education, training, or experience may vary by job function and that it would be difficult to provide generic guidance that would be sufficient for all specific job tasks. We decline to suggest that training should be limited, as the comments suggest, to the particular operation(s) that the employee performs as they relate to the person's functions. These CGMP requirements apply to many types of manufacturing operations of various size and complexity, so the training may vary depending on the circumstances and may include more than the employee's assigned functions.

(Comment 75) One comment states we should provide training materials such as texts, videos, Internet training, or seminars, to help companies properly train their employees.

(Response) We have no plans at this time to provide companies with training materials for their employees. We expect that most companies already have trained or will train their employees and that where additional training is needed to comply with these regulations, companies will develop the training materials that are appropriate for the functions their employees perform. We may consider providing guidance in the future if circumstances warrant such guidance.

G. What Supervisor Requirements Apply? (Final § 111.13)

Final § 111.13(a) requires you to assign qualified personnel to supervise the manufacturing, packaging, labeling, or holding of dietary supplements. Final § 111.13(a) derives from proposed § 111.13(a).

We did not receive comments specific to proposed § 111.13(a).

Final § 111.13(b) requires each supervisor you use to be qualified by education, training, or experience to supervise. Final 111.13(b) derives from proposed § 111.13(b) which would require you and your supervisors to be qualified by training and experience to supervise.

(Comment 76) Several comments ask us to revise the rule so that supervisors may be qualified by any combination of training or experience. These comments would revise proposed § 111.13(b) to read, ''supervisors must be qualified by education, training, and experience (or any combination thereof) to supervise the manufacturing, packaging, or holding of dietary ingredients and dietary supplements in compliance with this rule.'' One comment, however, would make an exception for quality control and sanitation supervisors, stating we should require these supervisors to have both training and experience.

(Response) Consistent with the change we made to proposed § 111.12(c), we are revising proposed § 111.13(b) to require the supervisors you use to be qualified by ''education, training, or experience.'' We acknowledge that some supervisory personnel may need a different range of education, training, or experience than others, and expect firms to determine the appropriate balance of education, training, and experience.

(Comment 77) Several comments say our use of the phrase ''you and the supervisors you use'' in proposed § 111.13(b) was unclear. According to these comments, the term ''you'' as defined in the proposal, is quite expansive and could be read so broadly as to require the Chief Executive Officer (CEO) of a company be ''qualified'' to supervise.

(Response) We agree that the phrase ''you and the supervisors you use'' could be clearer. Therefore, we are revising proposed § 111.13(b) to say that ''each supervisor whom you use'' must be qualified to supervise. Section 111.13(b) applies to any person who supervises the manufacturing, packaging, labeling, or holding of dietary supplements, even if that person also is an executive such as the CEO. Thus, final § 111.13(b) states, ''Each supervisor whom you use must be qualified by education, training, or experience to supervise.''

(Comment 78) Several comments say the term ''to supervise'' is ambiguous and would revise the rule to clarify what a supervisor must be qualified to supervise: The manufacture, packaging, or holding of dietary ingredients and dietary supplements. Another comment would revise proposed § 111.13(b) to clarify what type of training and experience are required so that firms would have more guidance as to what is expected to confirm that personnel are qualified.

(Response) We decline to revise the rule as suggested by the comments. We disagree that the term ''to supervise,'' which is commonly used in the industry, is ambiguous. These CGMP requirements apply to many types of manufacturing operations of various size and complexity, and the training must be suited to the circumstances.

H. Under This Subpart, What Records Must You Make and Keep? (Final § 111.14)

As discussed in this section, the final rule contains a new § 111.8 requiring you to establish and follow written procedures to fulfill the requirements of subpart B. Those written procedures are records. Therefore, we are adding a new § 111.14(a) requiring you to make and keep records in accordance with subpart P. Final § 111.14(b)(1) requires you to make and keep a record of the written procedures for fulfilling the requirements of subpart B.

The preamble to the 2003 CGMP Proposal invited comment on whether we should require documentation and records regarding each employee's training (68 FR 12157 at 12183). After considering comments and for the reasons discussed in the following paragraphs, § 111.14(b)(2) requires you to make and keep documentation of training, including the date of training, the type of training, and the person(s) trained.

We also invited comment on whether the final rule should contain requirements for documentation about consultants that you use (68 FR 12157 at 12183). We specifically suggested any such requirement include the consultant's name, address, qualifications, and a description of services provided. After considering the comments and for the reasons discussed in the following paragraphs, the final rule does not include any requirements to make and keep records regarding consultants.

(Comment 79) Several comments state employee training records are critical and should be required under the final rule. The comments explain that these records should show the content of the training, the date of the training, and the signature of the employee trained. These comments assert that a formal (written) GMP training program is necessary to track which employees have been trained in the CGMP requirements. These comments add, without a written and documented training program, it is likely that some employees may not receive sufficient training, or in some cases, any CGMP training at all. These comments say successful quality control programs are inextricably connected to appropriate training programs, and written documentation of employee training is an important safeguard to ensuring safe and accurately labeled dietary supplements. These comments also state it is already an industry standard to document training.

Other comments question our ability to evaluate whether a firm's employees have been adequately trained without written documentation of the training.

(Response) As discussed more fully in the discussion of subpart E in section X of this document, the final rule focuses on ensuring the quality of the dietary supplement at every stage of the production and process control system. Such a system begins with the proper training. We agree that documentation of employee training is necessary to track which employees have been trained in which operations. Therefore, final § 111.14(b)(2) requires you to keep documentation of training, including the date of the training, the type of training, and the person(s) trained.

(Comment 80) One comment says we should not require manufacturers to document and keep records regarding each employee's training. The comment says the rule should focus on end results and not on process.

(Response) We disagree with the comment. As we have explained in this section, each person engaged in an activity covered by these CGMP regulations must have the education, training, or experience to perform the person's assigned functions. Some employees will be considered qualified based in part on training taken as company employees. To show that such training is appropriate to the employee's functions and has in fact occurred, the training must be properly documented. This documentation is an important aspect of ensuring adequate training and, therefore, helping to ensure the result of having qualified employees who perform their functions properly.

(Comment 81) Several comments state the documentation of the training program should include the title of the person doing the training, an evaluation of the employee's understanding of the training, and recommendations for the frequency of refresher training. One comment describes a specific method for training and for tracking training. The comments state an evaluation of the employee's understanding of the training would ensure that employees who receive training understand what they have been taught.

(Response) We decline to require specific additional documentation of employee training. We believe a firm should have some flexibility in how it wants to document training.

(Comment 82) Several comments respond to our question as to whether the final rule should require documentation about consultants, including each consultant's name, address, qualifications, and a description of services provided. Several comments say that documenting this information is useful and could be done on a voluntary basis, but that such information is not necessary to ensure safe and accurately labeled supplements and, thus, should not be required. One comment notes that recommendations from consultants may or may not be used, and that a company should not have to explain at a later date why such decisions were made. Another comment asserts that we and the company may have different opinions on whether a consultant is qualified and that the consultant's qualification is not our concern if a product is not adulterated. One comment says documenting the name and services of the GMP consultants should be required to facilitate contact in case of need.

(Response) The proposal noted documentation of the name, address, qualifications, and services rendered for each consultant may help you know whom to contact and if questions arise concerning the advice that the consultant has given. Thus, our intent in suggesting such documentation was to help you rather than to make the information available for us to determine whether we agreed with you that a particular individual was qualified to be a consultant. However, the comments persuade us that such information is not necessary to help ensure dietary supplement quality. Therefore, the final rule does not require documentation regarding consultants.

VIII. Comments on Physical Plant and Grounds (Final Subpart C)

A. Organization of Final Subpart C

Proposed subpart C contained two provisions regarding physical plants. Table 4 of this document lists the sections in final subpart C and identifies the corresponding proposed sections that form the basis of the final rule.

TABLE 4.—DERIVATION OF SECTIONS IN FINAL SUBPART C

Final Rule	2003 CGMP Proposal
§ 111.15 What sanitation requirements apply to your physical plant and grounds?	§ 111.15
§ 111.16 What are the requirements under this subpart C for written procedures?	N/A
§ 111.20 What design and construction requirements apply to your physical plant?	§ 111.20
§ 111.23 Under this subpart C, what records must you make and keep?	§ 111.15(d)(3) and (e)(2)

B. Highlights of Changes to the Proposed Requirements for Physical Plant and Grounds

1. Revisions

The final rule:

- Reflects that the rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.
- Requires you to have documentation or otherwise be able to show that water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface, meets applicable Federal, State, and local requirements and does not contaminate the dietary supplement.

2. Changes After Considering Comments

The final rule:

- Includes requirements similar to the food CGMP requirements in § 110.20(a) for keeping the grounds bordering your physical plant in a condition that protects against contamination.
- Clarifies that sanitation supervisors can be qualified by education, training, or experience.
- Modifies the minimum requirements for water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface. Such water must, at a minimum, comply with applicable Federal, State, and local requirements and not contaminate the dietary supplement.
- Simplifies the sanitation requirements for toxic materials, bathroom facilities, and hand-washing facilities.
- Simplifies and clarifies the design requirements for floors, walls, and ceilings; fans and other air-blowing equipment; equipment that controls temperature and humidity; and the use of safety-type glass or glass-like materials.
- Requires written procedures for cleaning the physical plant and for pest control.
- Requires that you make and keep records of the written procedures.

C. General Comments on Proposed Subpart C

(Comment 83) Several comments say we should have different sanitation requirements for dietary ingredient manufacturers than for dietary supplement manufacturers. These comments state that the manufacture of synthetic or highly processed dietary ingredients includes extensive purification steps, especially toward the end of the manufacturing process, and that these steps remove contaminants that may have been introduced at earlier stages in the manufacturing process. These comments consider some stages of the dietary ingredient manufacturing process to not be subject to the same strict controls as those used for manufacturing finished dietary supplements.

(Response) As discussed in section VI of this document (subpart A), the final rule applies to persons who manufacture, package, label, or hold dietary supplements and who are not subject to an exclusion in § 111.1, and does not apply to establishments that only manufacture dietary ingredients. We addressed this comment in the response to comment 29.

(Comment 84) Some comments assert that one or more proposed requirements are unconstitutionally vague under the Fifth Amendment and are arbitrary and capricious under section 706(2)(B) of the APA. The comments would delete the following proposed requirements:

- § 111.15(e), which would require plumbing to be ''of an adequate size and

design and be adequately installed and maintained;''

• § 111.15(g), which would require bathrooms to be ''adequate'' and ''readily accessible; ''

• § 111.15(h), which would require hand-washing facilities ''to be adequate, convenient, and furnish running water at a suitable temperature;''

• § 111.15(h)(i), which would require hand-washing and, where appropriate, hand-sanitizing facilities ''at each location in your physical plant'' where good hygienic practices require employees to wash or to sanitize or both wash and sanitize their hands;

• § 111.20(a), which would require your physical plant to ''be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations;'' and

• § 111.20(d)(6), which would require aisles or working spaces between equipment and walls to be adequately unobstructed and of adequate width.

In general, these comments assert the 2003 CGMP Proposal did not define terms or phrases (such as ''adequately'' or ''at each location'') in a way that persons who are subject to the rule can discern the meaning of the term or phrase. These comments argue that the proposed rule imposes no limitations on enforcement officers on the exercise of their discretion and, thus, invites exercise of unbridled discretion and disparate decisionmaking.

(Response) As discussed in section V of this document, we disagree that the terms that the comments objected to in the 2003 CGMP Proposal are unconstitutionally vague, need to be defined, or may result in discriminatory enforcement. We are retaining the terms in the final rule.

D. What Sanitation Requirements Apply to Your Physical Plant and Grounds? (Final § 111.15)

1. Final § 111.15(a)

The preamble to the 2003 CGMP Proposal (68 FR 12157 at 12184) stated that we were not proposing requirements similar to the food CGMP requirements found in § 110.20(a) for keeping the grounds bordering your physical plant in a condition that protects against contamination of components or dietary supplements in order to limit the burden to manufacturers. However, we invited comment on whether we should include such requirements in a final rule. After considering the comments, we have drafted final § 111.15(a) to require you to keep the grounds of your physical plant in a condition that protects against the contamination of components, dietary supplements, or contact surfaces. The methods for adequate ground maintenance include:

• Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical plant so that it does not attract pests, harbor pests, or provide pests a place for breeding;

• Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed;

• Adequately draining areas that may contribute to the contamination of components, dietary supplements, or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests;

• Adequately operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed; and

• If your plant grounds are bordered by grounds not under your control, and if those other grounds are not maintained in the manner described in this section, you must exercise care in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous material that may be a source of contamination.

(Comment 85) Several comments say the final rule should require the maintenance of external areas similar to the food CGMP requirement at § 110.20(a) for keeping the grounds outside the facility adequately maintained. These comments state that such a requirement is basic, is equally important to facilities that manufacture conventional foods and to facilities that manufacture dietary supplements, and that there is no reason why this requirement should differ from food CGMPs. One comment asserts such a requirement is basic to the industry and it should not be dismissed as a burden to the industry. Some comments also assert that a provision similar to § 110.20(a) would help train staff and would explain to plant maintenance personnel what is required and why.

One comment says there should be some minimum requirement for sanitation and cleanliness in the area surrounding the plant and that requirements for drainage and trash removal should be adequate.

(Response) We agree that a requirement to maintain grounds is equally important for facilities that manufacture conventional foods and for facilities that manufacture dietary supplements. Although some requirements in § 110.20(a) are not strictly limited to drainage and trash disposal, the comment suggesting the requirements to maintain grounds be limited to drainage and trash disposal did not explain why, for example, it would not be as important for a facility that manufactures dietary supplements to maintain roads, yards, and parking lots so that they do not become a source of contamination as it already is for facilities that manufacture conventional foods. Therefore, the final rule is adding § 111.15(a), which is similar to § 110.20(a) with editorial revisions consistent with the rest of this final rule.

2. Final § 111.15(b)(1)

Final § 111.15(b)(1) (proposed § 111.15(a)) requires you to maintain your physical plant in a clean and sanitary condition. Final § 111.15(b)(2) requires you to maintain your physical plant in repair sufficient to prevent components, dietary supplements, or contact surfaces from becoming contaminated.

We did not receive comments specific to proposed § 111.15(a).

3. Final § 111.15(c)

Final § 111.15(c) (proposed § 111.15(b)) sets forth requirements for cleaning compounds, sanitizing agents, pesticides, and other toxic materials.

Final § 111.15(c) includes changes that we are making for clarity and consistency. We added other ''toxic'' materials because some paragraphs within final § 111.15(c) simply refer to the cleaning compounds, sanitizing agents, and pesticides as ''toxic materials,'' and because proposed § 111.15(b)(2) addressed the use and storage of toxic materials that are not within the general category of cleaning compounds, sanitizing agents, or pesticides.

Final § 111.15(c)(1) requires you to use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and that are safe and adequate under the conditions of use. Final § 111.15(c)(1) is similar to proposed § 111.15(b)(1), except that we inserted ''that are'' before ''safe and adequate.'' We consider this to be a nonsubstantive, editorial change. Proposed § 111.15(b)(1) was, itself, patterned after § 110.35(b)(1), which: (1) Requires cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures to be free from undesirable microorganisms and safe and adequate under the conditions of use and (2) provides that compliance may be verified by any effective means including purchase of these substances

under a supplier's guarantee or certification or examination of these substances for contamination.

(Comment 86) Several comments ask us to clarify our expectations with respect to substantiating that a cleaning compound or sanitizing agent is free from microorganisms of public health significance and is safe and adequate under conditions of use. Some comments suggest proposed § 111.15(b)(1) provide for the use of certifications or guarantees from a supplier because our investigators otherwise may not recognize such documents as evidence of compliance. Several comments say it is not necessary for a manufacturer to test these types of products, and that a continuing product guarantee, combined with a statement of intended use from the manufacturer of the cleaning compound or sanitizing agent, should satisfy the requirements.

(Response) When assessing compliance with final § 111.15(c)(1), we would not treat a firm that manufactures, packages, labels, or holds a dietary supplement differently than we would treat a facility that manufactures, packages, labels, or holds conventional foods. Therefore, we intend to accept, as the comments request, a supplier's guarantee or certification that a cleaning compound or sanitizing agent is free from microorganisms of public health significance and is safe and adequate under the conditions of use for the purpose of determining compliance with final § 111.15(c)(1).

Final § 111.15(c)(2) requires you to not use or hold toxic materials in a physical plant in which components, dietary supplements, or contact surfaces are manufactured or exposed, unless those materials are necessary: (1) To maintain clean and sanitary conditions, (2) for use in laboratory testing procedures, (3) for maintaining or operating the physical plant or equipment, or (4) for use in the plant's operations.

We did not receive comments specific to proposed § 111.15(b)(2). We have made a nonsubstantive edit to § 111.15(c)(2) by moving ''contact surfaces'' to be the last item on the list.

Final § 111.15(c)(3) requires you to identify and hold cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials in a manner that protects against contamination of components, dietary supplements, or contact surfaces. Final § 111.15(c)(3) is similar to proposed § 111.15(b)(3).

We did not receive comments specific to proposed § 111.15(b)(3), but replaced ''toxic cleaning compounds'' with ''cleaning compounds,'' and added ''other toxic materials.''

4. Final § 111.15(d)

Final § 111.15(d) (proposed § 111.15(c)) sets forth requirements for pest control. Section § 111.15(d) is almost identical to proposed § 111.15(c).

Final § 111.15(d)(1) requires you to not allow animals or pests in any area of your physical plant. Final § 111.15(d)(1) allows guard or guide dogs in some areas of your physical plant if the presence of the dogs will not result in contamination of components, dietary supplements, or contact surfaces. Final § 111.15(d)(2) requires that you take effective measures to exclude pests from your physical plant and to protect against the contamination of components, dietary supplements, and contact surfaces on the premises by pests. Final § 111.15(d)(3) requires that you not use insecticides, fumigants, fungicides, or rodenticides unless you take precautions to protect against the contamination of your components, dietary supplements, or contact surfaces.

(Comment 87) Several comments claim proposed § 111.15(c) would require that sealed equipment outside of the plant (e.g. storage tanks, vessels, piping) be enclosed to prevent pests from roaming around these areas. The comments say there is no need to shelter outdoor equipment if it is properly sealed. These comments state that dietary supplements are sometimes manufactured in extensive, highly automated facilities in which large tanks and vessels are interconnected via piping, and that in these cases ''the physical plant'' and ''the equipment in the plant'' converge so that some or much of the equipment is effectively located outdoors. Thus, the comments ask us to revise proposed § 111.15(c) to clarify that it applies only to interior areas of the physical plant.

(Response) Equipment such as that described by the comments, if properly sealed, should protect components, dietary supplements, and contact surfaces from contamination with pests. Final § 111.15(d) does not require that sealed equipment outside of the plant, such as storage tanks, vessels, or piping, be enclosed, e.g., inside a building. Final § 111.15(d)(2) requires that you take effective measures to exclude pests from your physical plant and to protect against the contamination of components, dietary supplements, or contact surfaces on the premises by pests. Moreover, final § 111.15(a) includes several requirements designed to limit or exclude pests around all parts of the exterior of your physical plant. Therefore, although you do not have to enclose your outside equipment, you must take measures to exclude pests from areas outside of the plant.

5. Final § 111.15(e)

Final § 111.15(e) (proposed § 111.15(d)) sets forth requirements for the water supply of your physical plant.

Final § 111.15(e)(1) requires that you must provide water that is safe and sanitary at suitable temperatures and under pressure as needed for all uses where water does not become a component of the dietary supplement.

We did not receive comments specific to proposed § 111.15(d)(1). We have modified the phrase ''safe and of adequate sanitary quality'' to read ''safe and sanitary.'' To avoid confusion with the definition of ''quality'' we have adopted solely for purposes of this final rule, we deleted the references to ''quality'' as it applies to water standards. We consider this change to be nonsubstantive and still require water that is not a component of a dietary supplement to meet a safe and sanitary standard.

Final § 111.15(e)(2) requires that water used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface, must, at a minimum, comply with applicable Federal, State, and local requirements and not contaminate the dietary supplement. Final § 111.15(e)(2) derives from proposed § 111.15(d)(2) which would require that water that contacts components, dietary supplements, or any contact surfaces must, at a minimum, comply with the applicable National Primary Drinking Water (NPDW) regulations and any State and local government requirements. Final § 111.15(e)(2) includes changes we are making after considering comments discussed in the following paragraphs.

(Comment 88) Several comments state the water quality that is required for conventional foods is sufficient for dietary supplements. The comments argue that no additional water standards are listed in the CGMPs for low-acid canned foods in part 113 or in the CGMPs for acidified foods in part 114. These comments argue that, if ''safe and of adequate sanitary quality'' is sufficient to ensure the quality of the water used in most food products, then it is also adequate to ensure the quality of the water used in dietary supplements.

Other comments would revise the final rule to allow different standards and requirements for water that contacts or is used in dietary supplements

compared to water that contacts components, including dietary ingredients. These comments state current food CGMP regulations require only that water supplies that contact food (defined to include ingredients and raw materials) be ''safe and of adequate sanitary quality.'' These comments say that this would be consistent with the act's basis for CGMP requirements for foods, i.e., that food is not prepared ''under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health'' (section 402(a)(4) of the act). Several comments state the final rule should adopt a similar rationale for components, including dietary ingredients. These comments explain that components, including dietary ingredients, are not in a form in which they will be consumed and are subject to further processing prior to consumption.

Several comments say that requiring water used for cleaning contact surfaces to meet Environmental Protection Agency regulations is an unnecessary burden for companies that do not have access to municipal water. According to these comments, potable water should be sufficient.

(Response) In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12185), we stated that water should, at a minimum, be potable and that water that is ''safe and of adequate sanitary quality'' should be potable. We also said water that contacts components, dietary supplements, or contact surfaces should, at a minimum, meet the Environmental Protection Agency's NPDW regulations and State, and local requirements. We proposed to require that water used in operations where water contacts components, dietary supplements, or any contact surfaces meet the NPDW regulations because of the potential for contamination if water were used that did not adhere to the microbial standards, for example, in the NPDW regulations. Finally, we stated these requirements were minimum requirements and that water that is more pure than that required under the NPDW regulations may be desired.

The comments stated some manufacturers may not have access to municipal water, and therefore, that meeting the NPDW regulations for cleaning contact surfaces would be too burdensome. These comments asserted that potable water would be sufficient. The comments do not provide a definition of ''potable water.'' We have defined ''potable water,'' in the regulations on interstate conveyance sanitation in 21 CFR part 1250 to be, in part, water that meets the standards prescribed in the Environmental Protection Agency's NPDW regulations in 40 CFR part 141.

We would consider it to be a rare situation where a dietary supplement manufacturer uses well water and has no access to municipal water. Nonetheless, to the extent that a manufacturer uses water that is not subject to Federal oversight, the manufacturer would have to comply with any State or local regulations that apply to food manufacturing facilities using such water in food processing.

Manufacturers that use water from a municipal source, which is subject to the Environmental Protection Agency NPDW regulations, should not be subject to a lesser standard in this final rule than what is already required of them by the Environmental Protection Agency. Thus, to accommodate manufacturers subject to the Environmental Protection Agency's NPDW regulations for the water that they use in the manufacture of dietary supplements, as well as those dietary supplement manufacturers who are not subject to the Environmental Protection Agency's NPDW regulations, we are modifying the rule to state water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface, must, at a minimum, comply with applicable Federal, State, and local requirements and not contaminate the dietary supplement. We decline to use ''safe and of adequate safety'' that some comments state is sufficient because it is for conventional foods. We believe that requiring that water comply with Federal, State and local requirements and not contaminate dietary supplements provides a clear standard as to what is required.

(Comment 89) Some comments assert that water that is used to manufacture components or dietary ingredients where such components or dietary ingredients are subject to further processing prior to consumption, should be subject to the ''safe and of adequate sanitary quality'' standard in § 110.37.

(Response) We acknowledge that such components and dietary ingredients are subject to the requirement in § 110.37. If the manufacturers do not fall within the scope of final § 111.1, such manufacturers would be subject to the CGMP requirements in part 110.

To the extent that such comments request the ''safe and of adequate sanitary quality'' language apply to water used in the manufacture of a dietary supplement, we decline to make that change. Water that is safe and sanitary would not necessarily comply with, for example, the NPDW regulations. A requirement stating ''safe and of adequate sanitary quality'' or, as stated in the final rule, the requirement of ''safe and sanitary'' could be seen as a lesser standard than water that complies with ''applicable Federal, State, and local requirements.'' We want to make clear that you must comply with applicable Federal, State, and local requirements related to the water that you use for food processing that would otherwise be required of you, and not to some lesser standard that you may consider is ''safe and sanitary'' when water is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts a component, dietary supplement, or any contact surface. Foreign manufacturers would need to comply with the water standard required in this final rule and achieve the same level of performance as is required of domestic manufacturers. The water used in domestic or foreign manufacturing must not contaminate the dietary supplement. To clarify that the water used, whether by a domestic or foreign manufacturer, must not be a source of contamination, we are adding the words ''and not contaminate the dietary supplement'' in final § 111.15(e)(2). We also want to make it clear that water includes what is in the water, e.g., any of its contaminants in addition to H_2O. For example, when we speak of drinking water, we do not just mean the H_2O, we mean the iron, lead, sulfur, and any other contaminants contained in the water.

(Comment 90) Several comments suggest water should meet some or all standards of the USP monograph for sterile, purified water and say that the standard in the USP monograph is a higher, and presumably safer, standard than the NPDW standard. The comments state the USP's water deionization and purification systems requirements are already common in the industry.

(Response) We do not discourage firms from using water in dietary supplement manufacturing that meets USP standards, including deionized or purified water, but we do not require, as a CGMP, the use of USP standards. This final rule sets forth minimum requirements for persons who manufacture, package, label, or hold a dietary supplement. Thus, firms may use water that exceeds our minimum requirements.

(Comment 91) The preamble to the 2003 CGMP Proposal recognized that foreign firms might not be subject to Environmental Protection Agency water

requirements or adhere to such requirements, but also stated that water quality is an important part of CGMP (68 FR 12157 at 12185). Thus, in the preamble to the 2003 CGMP Proposal, we invited comment on how we might ensure that foreign firms meet the same water quality requirements as domestic firms. Several comments respond to our request for comments specific to the applicability of the water standards to foreign firms. Several comments recommend we not distinguish between domestic and foreign firms with regard to water quality. The comments claim all firms must compete on a ''level playing field.'' These comments state water quality standards vary from country to country, and many countries do not have requirements that are comparable to those in the United States. The comments say foreign manufacturers should not be permitted to import products into the United States that do not meet the same safety standards as domestic goods.

Other comments ask us to consider the water quality requirement to be met if the water complies with the NPDW standard or any equivalent water quality standard that is ensured by a foreign public agency.

(Response) We agree that foreign firms should be required to meet the water safety and sanitary requirements required of domestic firms and achieve the same level of performance of domestic firms. As discussed in this section, foreign firms are required to meet all requirements and would need to comply with their own national or local water safety requirements and not contaminate the dietary supplement.

(Comment 92) One comment would combine proposed § 111.15(d)(1) and (d)(2) into a single paragraph. The comment says the two proposed paragraphs are redundant. Proposed § 111.15(d)(1) would require that you provide water that is safe and of adequate sanitary quality, at suitable temperatures, and under pressure as needed, in all areas where water is necessary for: (1) Manufacturing dietary ingredients or dietary supplements; (2) making ice that comes in contact with components, dietary ingredients, dietary supplements, or contact surfaces; (3) cleaning any surface; and (4) employee bathrooms and hand-washing facilities. Proposed § 111.15(d)(2) would require that water that contacts components, dietary ingredients, dietary supplements, or any contact surface must at a minimum comply with the NPDW regulations prescribed by the Environmental Protection Agency under 40 CFR part 141 and any State and local government requirements.

(Response) We disagree that proposed § 111.15(d)(1) and (d)(2) were redundant. For example, as described in the proposed sections, nonpotable water that would have been ''safe and of adequate sanitary quality'' for use in flushing toilets may not have been ''safe and of adequate sanitary quality'' for use in the manufacture of a liquid dietary supplement.

Final § 111.15(e)(1) requires that you provide water that is safe and sanitary, at suitable temperatures, and under pressure as needed, for all uses where water does not become a component of the dietary supplement. Final § 111.15(e)(2) requires that water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface, must, at a minimum, comply with applicable Federal, State, and local requirements and not contaminate the dietary supplement. As an example of how the requirements would apply, water that contains lead at a level that is 20 times higher than the maximum accepted level in the Environmental Protection Agency's NPDW standards for lead may not be safe for use in the manufacture of dietary supplement that is consumed in four 2-ounce portions per day, but may be safe for use in cleaning the floors of the physical plant. Therefore, to emphasize that water that is ''safe and sanitary'' may be different depending on its use, the final rule continues to separate § 111.15(e)(1) and (e)(2) (formerly proposed § 111.15(d)(1) and (d)(2)).

Additionally, to emphasize the importance of the water that is used in the manufacture of a dietary supplement, where the water is used in a manner such that the water may become a component of the dietary supplement, final § 111.23(c) (proposed § 111.15(d)(3)) requires you to have documentation and keep records that such water meets the requirements of final § 111.15(e)(2). In contrast, there is no corresponding requirement for documentation in final § 111.23 that other water, such as water that is used to clean floors or used in employee bathrooms, meets requirements of final § 111.15(e)(1).

(Comment 93) Several comments state, if we retain a water standard requirement based on the Environmental Protection Agency NPDW standard, then it is important to include provisions recognizing the acceptability of municipal water sources and the frequency of testing required for other water sources. Some comments recommend water should meet the USP standard for purified water and point out that the USP standard provides an assurance of the water's consistency and provides a system that can be monitored.

Several comments suggest we include timetables for water testing or describe water testing frequency requirements. These comments state we should apply something analogous to the proposed requirements for infant formula which would require manufacturers to conduct the tests with sufficient frequency to ensure that the water meets the Environmental Protection Agency's NPDW standard, but not less frequently than annually for chemical contaminants, every 4 years for radiological contaminants, and weekly for bacteriological contaminants. Other comments refer to the amendments to the bottled water regulations at § 165.110 which require a minimum yearly monitoring of source water and finished bottled water products for chemical contaminants for which allowable levels have been established in the bottled water quality standard.

(Response) Final § 111.23(c) requires you to have documentation that water, when used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts a component, dietary supplement, or contact surface, meets the requirements of final § 111.15(e)(2). You must meet the requirement for final § 111.15(e)(2) at the point of use, rather than at the point of delivery, i.e., at the point the water may become a component of the dietary supplement, such as when the water contacts components, dietary supplements, or any contact surface (such as when the water comes out of the faucet or comes out of a spigot from a holding tank where you store water). Thus, you must ensure that the water used in a manner such that the water may become a component of the dietary supplement, not the water source before it enters your facility, meets the NPDW regulations, or if not subject to the NPDW regulations, that it meets any other applicable Federal, State, and local requirements and does not contaminate the dietary supplement.

For example, if the water that enters your facility is subject to the Environmental Protection Agency NPDW regulations, then the water must comply with such requirements at the point of use, i.e., when it contacts the components, dietary supplement, or any contact surface (such as when the water comes out of the faucet or out of a spigot from a holding tank where you store water). You could rely on a certificate of analysis under final § 111.75(a)(2)(ii)

from the supplier of the water (e.g., the municipality) to ensure that the water entering your facility complies the applicable Federal, State, and local requirements. However, you must ensure that nothing happens to the water that may contaminate the water once it enters your facility and before the water may become a component of the dietary supplement at the point of use. Certain contaminants or microorganisms may be introduced into the water from the facility. Thus, you may need to establish specifications and procedures to prevent contamination from pipes through which the water travels in the facility or from vessels in which the water is held in the facility prior to use. You may need to test for certain contaminants, e.g., lead or microorganisms, at point of use to ensure there is no contamination of the water within your facility. Such tests may not need to include all of the chemical, microbiological, or contaminant testing already certified by the supplier to determine whether the water entering your facility complies with Federal, State and local requirements. Rather, you would need to evaluate what, if any, introductions of contaminants are likely to occur within your facility and determine whether additional tests are needed to verify that the water, at point of use, will comply with Federal, State, and local requirements and not contaminate the dietary supplement. Alternatively, you may decide not to rely on a certificate of analysis and instead conduct your own testing at point of use to determine if the water complies with applicable Federal, State, and local requirements. We decline to set out testing requirements or frequency of testing in this final rule in lieu of giving manufacturers the flexibility to decide on the appropriate testing and frequency of such testing to ensure that the water meets the requirements in final § 111.15(e)(2). We may consider issuing guidance, as needed, on our recommendation for testing based on water sources and the purposes for which the water is used. If you rely on a certificate of analysis from the supplier of the water, we recommend that you qualify your facility by conducting appropriate tests at the point of use to verify that no other tests are necessary or that any additional tests you have chosen are sufficient to establish that the water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements or any contact surface, meets the requirements of final § 111.15(e)(2). We also recommend that you requalify your facility at the point of use at appropriate intervals.

If you use water from a private source, you must use water that complies with any State and local requirement and does not contaminate the dietary supplement. You may need to perform appropriate water treatment procedures, including filtration, sedimentation, and chlorination to satisfy final § 111.15(e)(2).

(Comment 94) Several comments would delete proposed § 111.15(d)(2), arguing that it is unnecessary to state a requirement that water meet the Environmental Protection Agency's NPDW standards. These comments state that if water is used in processing or at critical points in the cleaning process, then a manufacturer will already have established specifications for its appropriate use.

(Response) We agree that a manufacturer will need to establish specifications, under final § 111.70(a), for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement, and for water that is used in a manner such that the water may become a component of the dietary supplement. For reasons set forth in response to comment 88, final § 111.15(e)(2) establishes the minimum standards for water that will be used in a manner such that the water may become a component the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface. Thus, we disagree that proposed § 111.15(e)(2) be eliminated.

6. Final § 111.15(f)

Final § 111.15(f) (proposed §111.15(e)) sets forth requirements for the plumbing of your physical plant.

Final § 111.15(f) requires your plumbing to be of an adequate size and design and be adequately installed and maintained to: (1) Carry sufficient amounts of water to required locations throughout the physical plant; (2) properly convey sewage and liquid disposable waste from your physical plant; (3) avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition; (4) provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and (5) not allow backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms and hand-washing facilities.

We did not receive comments specific to proposed § 111.15(e), other than comments arguing that certain text was unconstitutionally vague and arbitrary and capricious. We address those comments in section V of this document.

7. Final § 111.15(g)

Final § 111.15(g) (proposed § 111.15(f)) sets forth requirements for sewage disposal and requires you to dispose of sewage into an adequate sewage system or through other adequate means.

We did not receive comments specific to proposed § 111.15(f).

8. Final § 111.15(h)

Final § 111.15(h) (proposed § 111.15(g)(1)) sets forth requirements for the bathrooms of your physical plant. Final § 111.15(h) requires you to provide your employees with adequate, readily accessible bathrooms, and that the bathrooms be kept clean and not be a potential source of contamination to your components, dietary supplements, or contact surfaces.

(Comment 95) Several comments state companies should be given flexibility in designing their bathrooms. These comments assert the food CGMP requirements allow flexibility in bathroom design, so the dietary supplement CGMP rule should do the same. The comments would delete proposed § 111.15(g)(1) through (g)(3), which pertained to: (1) Keeping the bathrooms in good repair at all times; (2) providing self-closing doors; and (3) providing doors that do not open into areas where components, dietary ingredients, dietary supplements, or contact surfaces are exposed to airborne contamination, except where alternate means have been taken to protect against contamination.

(Response) We agree that it is unnecessary to require specific bathroom features such as those in proposed § 111.15(g)(1) through (g)(3) because you may be able to achieve compliance through other means better suited to your operations. Accordingly, we are revising the rule by deleting proposed § 111.15(g)(1) through (g)(3) as requested by the comments. However, we continue to believe that mechanisms such as self-closing doors and doors that do not open onto areas where components, dietary supplements, or contact surfaces are exposed to

contamination will help protect against contamination.

9. Final § 111.15(i)

Final § 111.15(i) (proposed § 111.5(h)) sets forth requirements for the hand-washing facilities of your physical plant. Final § 111.15(i) requires you to provide hand-washing facilities that are designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

Final § 111.15(i) differs from the proposal in that the proposal would list six specific features of a hand-washing facility, such as effective hand-cleaning and sanitizing preparations (proposed § 111.15(h)(2)), air driers, sanitary towel service, or other suitable drying devices (proposed § 111.15(h)(3)), and trash bins that are constructed to protect against recontamination (proposed § 111.15(h)(4)).

(Comment 96) Several comments state we should give firms the flexibility to design their hand-washing facilities. According to these comments, substituting the word ''may'' for the word ''must'' would accomplish this. The comments argue that, as with bathrooms, an overall sanitation requirement should be sufficient, and that, as long as there is a strong and enforceable standard, firms should have the flexibility to adopt only those measures that are needed to meet the underlying requirement.

(Response) We agree that it is unnecessary to require specific hand-washing mechanisms because you may be able to achieve compliance through other means better suited to your operations. However, we disagree that an overall sanitation requirement would be sufficient, because such a requirement would not clearly state the purpose of the requirement, which is to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface.

We are revising proposed § 111.15(h) (final § 111.15(i)) in the final rule in two respects. First, the final rule states that the hand-washing facilities are to be designed to ensure that an employee's hands are not a source of contamination. Second, final § 111.15(i) states that the hand-washing facilities are to be adequate, convenient, and furnish running water at suitable temperatures but does not provide the specific hand-washing mechanisms detailed in the 2003 CGMP Proposal.

10. Final § 111.15(j)

Final § 111.15(j) (proposed § 111.15(i)) sets forth requirements for trash disposal at your physical plant. Final § 111.15(j) requires that you convey, store, and dispose of trash to: (1) Minimize the development of odors; (2) minimize the potential for trash to attract, harbor, or become a breeding place for pests; (3) protect against contamination of components, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant; and (4) control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.

(Comment 97) One comment suggests deleting proposed § 111.15(i)(1) concerning minimizing the development of odors, because, the comment claimed, minimizing odors is not a ''true'' CGMP requirement.

(Response) We disagree that minimizing the development of odors is not part of CGMP. Odor from trash is often an indication of problems with microbial contamination, such as decomposition, decay, and the growth of harmful bacteria. In addition, odor from trash can attract pests. By conveying, storing, and disposing of trash to minimize the development of odors, you will help reduce the potential for problems with microbial contamination and pests.

11. Final § 111.15(k)

Final § 111.15(k) (proposed § 111.15(j)) sets forth requirements for sanitation supervisors at your physical plant. Final § 111.15(k) requires that you assign one or more employees to supervise overall sanitation. Each supervisor must be qualified by education, training, or experience to develop and supervise sanitation procedures. Final § 111.15(k) differs from proposed § 111.15(j) in that the proposal would require that each supervisor be qualified by training and experience.

(Comment 98) Several comments suggest revising proposed § 111.15(j) to state that sanitation supervisors may be qualified by education, training, or experience (or any combination thereof) to develop and supervise sanitation procedures. In contrast, several comments say that sanitation supervisors should be qualified by both training and experience.

(Response) Consistent with our response to comment 76 in section VII of this document, final § 111.15(k) provides that sanitation supervisors, like other supervisors, must be qualified by education, training, or experience to develop and supervise sanitation procedures. As we also stated in response to comment 76, we acknowledge that some supervisory personnel may need a different range of education, training, or experience than others. However, we have decided to give firms the flexibility to decide the appropriate amount of education, training, or experience for a given job function. If that includes a combination of attributes, the firm should select and train employees accordingly.

E. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.16)

We received many comments that recommend written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to comments on specific provisions in the same section.

We are adding a new final § 111.16 entitled ''What Are the Requirements Under This Subpart for Written Procedures?,'' to require you to establish and follow written procedures for fulfilling certain requirements of subpart C. You must establish and follow written procedures for cleaning the physical plant and for pest control.

F. What Design and Construction Requirements Apply to Your Physical Plant? (Final § 111.20)

Final § 111.20 addresses physical plant design and construction requirements.

1. Final § 111.20(a) and (b)

Final § 111.20(a) and (b) require that any physical plant that you use in the manufacturing, packaging, labeling, or holding of dietary supplements: (1) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations and (2) have adequate space for the orderly placement of equipment and holding of materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mixups of components and dietary supplements during manufacturing, packaging, labeling, or holding.

We did not receive comments specific to proposed § 111.20(a) or (b), other than comments arguing that certain text in proposed § 111.20(b) was unconstitutionally vague and arbitrary and capricious. We address those comments in this section and section V of this document.

2. Final § 111.20(c)

Final § 111.20(c) requires that any physical plant you use in the manufacturing, packaging, labeling, or holding of dietary supplements provide for the use of proper precautions to reduce the potential for mixups or contamination of components, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material.

Under final § 111.20(c) your physical plant must have, and you must use, separate or defined areas of adequate size or other control systems, such as computerized inventory controls or automated systems of separation, to prevent contamination and mixups of components and dietary supplements during the following operations: (1) Receiving, identifying, holding, and withholding from use, components, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, labeling, or holding of dietary supplements; (2) separating, as necessary, components, dietary supplements, packaging, and labels that are to be used in manufacturing from components, dietary supplements, packaging, or labels that are awaiting material review and disposition decision, reprocessing, or are awaiting disposal after rejection; (3) separating the manufacturing, packaging, labeling, and holding of different product types including different types of dietary supplements and other foods, cosmetics, and pharmaceutical products; (4) performing laboratory analyses and holding laboratory supplies and samples; (5) cleaning and sanitizing contact surfaces; (6) packaging and label operations; and (7) holding components or dietary supplements.

(Comment 99) Several comments would change ''computerized inventory controls'' to ''adequate inventory controls'' in proposed § 111.20(c). The comments say that a requirement to use a computerized system is too prescriptive and that inventory controls that are not computerized may be equally effective in achieving compliance with proposed § 111.20(c).

(Response) These comments may have misinterpreted proposed § 111.20(c). Computerized inventory controls are an example of the type of system that may be appropriate; § 111.20(c) does not require you to have a computerized system in the first instance. Thus, final § 111.20(c) continues to use computerized inventory controls as an example of a central system.

(Comment 100) Several comments ask us to clarify the degree of separation that is intended under proposed § 111.20(c) when it referred to ''separate or defined areas'' of a physical plant. These comments state that it is unclear if we expect a firm not to manufacture multiple products in a single room or area. The comments state that, if this is the case, this would be equivalent to the drug CGMP requirements and would be excessive. The comments argue that, if the proper controls are in place, manufacturing and packaging of multiple products is possible in a single room or area without compromising product identity, quality, strength, purity, and composition.

(Response) Final § 111.20(c) states that you must have and use separate or defined areas of adequate size or other control systems, such as computerized inventory controls or automated systems of separation. The preamble of the 2003 CGMP Proposal explained that if your physical plant does not allow for physically separate areas, you could develop an alternative approach for segregating components and dietary supplements at points when they are received, stored, and rejected (68 FR 12157 at 12188). We interpret the comments as asking whether alternative approaches for segregating products could be used, even if physically separate areas were available in a facility, so that different materials could be processed in the same area. Final § 111.20(c) allows you to use ''separate or defined areas of adequate size or other control systems;'' thus, you can comply with this requirement by manufacturing multiple products in the same room or area instead of using a physically separate location, as long as you have systems in place to prevent contamination and mixups of components and dietary supplements.

3. Final § 111.20(d)

Final § 111.20(d) requires that any physical plant you use in the manufacturing, packaging, labeling, or holding of dietary supplements be designed and constructed in a manner that prevents contamination of components, dietary supplements, or contact surfaces.

Final § 111.20(d)(1) requires the design and construction to include: (1) Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair; (2) fixtures, ducts, and pipes that do not contaminate components, dietary supplements, or contact surfaces by dripping or other leakage or condensate; (3) adequate ventilation or environmental control equipment, such as air flow systems, including filters, fans, and other air-blowing equipment, that minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate components, dietary supplements, or contact surfaces; (4) equipment that controls temperature and humidity, when such equipment is necessary to ensure the quality of the dietary supplement; and (5) aisles or working spaces between equipment and walls that are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, dietary supplements, or contact surfaces with clothing or personal contact.

Final § 111.20(d)(1)(i) through (d)(1)(v) is similar to proposed § 111.20(d)(1), (d)(2), (d)(3), (d)(5), and (d)(6), respectively. Additionally, as explained in the following paragraphs, we have made other changes to proposed § 111.20(d)(1) (final § 111.20(d)(1)(i)) and proposed § 111.20(d)(5) (final § 111.20(d)(1)(iv)).

(Comment 101) Several comments argue that the requirement of proposed § 111.20(d)(1) that floors, walls, and ceilings be made of ''smooth and hard surfaces,'' if read literally, could be interpreted to prohibit the use of ceilings with drop-in tiles. These comments assert that, while there may be areas in a manufacturing plant where drop-in ceilings are inappropriate given the height of the ceiling, the nature of the product, or the type of operation conducted in that area, such ceilings are adequate in many areas of a manufacturing facility, and certainly are appropriate in places where product is labeled or stored. The comments argue that replacing such ceilings with surfaces that are ''smooth and hard'' is unnecessary. Several other comments argue that they could find no precedent in any food CGMP regulations for a provision specifying ''smooth and hard surfaces'' for ceilings, but did identify a precedent in the section of drug CGMP requirements relating to ''aseptic processing.'' The comments state that adopting such a drug CGMP requirement is inappropriate for dietary supplements.

The comments say the overall purpose of proposed § 111.20(d)(1) should be to ensure that facilities can be kept in a clean and sanitary condition. The comments would revise proposed § 111.20(d)(1) to require physical plants to have surfaces that can be adequately cleaned, but would give manufacturers the flexibility to use appropriate surfaces in different parts of a plant.

The comments also argue that the rule's specificity establishes a conundrum for certain manufacturers to conform to other Federal regulations,

e.g., Occupational Safety and Health Administration (OSHA) noise levels. The comments argue that firms should be allowed to simultaneously conform to both OSHA and FDA requirements.

(Response) We agree that a smooth and hard surface may not be necessary in every case to prevent contamination of the dietary supplement. However, you may need floors, walls, and ceilings that are constructed of smooth and hard surfaces to prevent contamination of the dietary supplement when, for example, physical attributes of components (e.g., particle size or electrostatic charge) would make it difficult to keep floors, walls, and ceilings clean. Consequently, we conclude that a requirement that the physical plant have floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair to prevent contamination of the dietary supplement is sufficient. We are revising final § 111.20(d)(1) to remove the language concerning smooth and hard surfaces. The final rule gives you the flexibility to determine how best to construct your facility in order to prevent contamination and to ensure the quality of the dietary supplements you manufacture, package, label, or hold.

Section 111.20(d)(1)(ii) of the final rule (proposed § 111.20(d)(2)) requires your physical plant design and construction to have fixtures, ducts, and pipes that do not contaminate components, dietary supplements, or contact surfaces by dripping or other leakage, or condensate. Final § 111.20(d)(1)(iii) (proposed § 111.20(d)(3)) pertains to adequate ventilation or environmental control equipment. We added ''or other leakage'' to clarify that the requirement relates to ''leakage'' regardless of whether the leakage is in the form of ''dripping.''

(Comment 102) Proposed § 111.20(d)(5) would require your physical plant design and construction to include equipment that controls temperature and humidity. Several comments suggest adding a qualifier to the temperature and humidity control requirements so that controls are only required as necessary to prevent adulteration. The comments state there is adequate evidence that temperature and humidity do not stimulate reproduction of microorganisms and pests in dietary supplements. The comments also argue that retesting older ingredients stored in an uncontrolled environment and subjected to heat, cold, and ambient humidity produced no evidence of reproduction of microorganisms. According to the comments, temperature and humidity may present issues with raw, unprocessed botanical ingredients or animal-derived ingredients, but there is no proven issue with the powdered botanical and animal derived ingredients used by the dietary supplement industry.

Several comments argue against requiring temperature and heat controls, asserting that most equipment used to manufacture dietary supplements is often cleaned with large amounts of hot water, and therefore temperature and humidity controls are not practical.

(Response) We agree that controls for temperature and humidity should only be required when necessary to ensure the quality of the dietary supplement, and we are revising final § 111.20(d) accordingly. However, we disagree that there is adequate evidence that temperature and humidity do not stimulate reproduction of microorganisms in dietary supplements. It is well-recognized that microorganisms such as bacteria will grow in a warm environment and that microorganisms, such as molds, will grow in a moist environment. In addition, if the comments are suggesting that this final rule should only include requirements that derive from specific, already known examples that the absence of a requirement directly led to a problem with a dietary supplement, we disagree. CGMP requirements can help prevent products from becoming adulterated during the manufacturing process, and, in certain cases, controlling temperature and humidity may be necessary to ensure the quality of the dietary supplement.

With respect to the comments stating that using hot water to clean equipment makes control of temperature and humidity impractical, we advise that a firm unable to control temperature and humidity in those parts of its facility where control is necessary to ensure the quality of the dietary supplement because it uses hot water to clean equipment would not be in compliance with final § 111.20(c). The provision requires that your physical plant have, and that you use, separate and defined areas of adequate size, or other control systems, to prevent contamination during operations such as cleaning contact surfaces (final § 111.20(c)(5)).

Final § 111.20(d)(2) (proposed § 111.20(d)(4)) requires that, when fans and other air-blowing equipment are used, such fans and equipment be located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, dietary supplements, or contact surfaces.

(Comment 103) Several comments interpret proposed § 111.20(d)(4) as requiring fans and air-blowing equipment. These comments state this type of equipment is not always needed and may, in some instances, be more likely to cause adulteration than prevent it. The comments ask us to clarify that fans and other air-blowing equipment are only required when they are necessary to prevent adulteration.

(Response) Proposed § 111.20(d)(4) was intended to require that any fans and other air-blowing equipment you use be located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, dietary supplements, or contact surfaces.

Nevertheless, given the comments' misinterpretation, we are revising proposed § 111.20(d)(4) (final § 111.20(d)(2)) to state that, ''When fans and other air-blowing equipment are used,'' those fans and equipment must be located and operated in a manner that minimizes the potential for contamination by microorganisms and particulate matter. This should clarify that the rule does not mandate the use of fans and air-blowing equipment.

(Comment 104) Some comments state that exhaust and venting equipment can, under certain circumstances, be a source of microbial contamination. The comments would revise proposed § 111.20(d)(4) to read: ''Fans and other air-blowing or exhaust and venting equipment located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, dietary ingredients, dietary supplements, or contact surfaces.''

(Response) We decline to revise the rule as suggested by these comments as there is no need to do so. We consider exhaust equipment and venting equipment to be types of fans or air-blowing equipment and therefore covered by the term ''fans and other air-blowing equipment.''

4. Final § 111.20(e)

Final § 111.20(e) (proposed § 111.20(e)) requires that any physical plant that you use in the manufacturing, packaging, labeling, or holding of dietary supplements provide adequate light in: (1) All areas where components or dietary supplements are examined, processed, or held; (2) all areas where contact surfaces are cleaned; and (3) hand-washing areas, dressing and locker rooms, and bathrooms.

We did not receive any comments specific to proposed § 111.20(e).

5. Final § 111.20(f)

Final § 111.20(f) (proposed § 111.20(f)) requires that any physical

plant you use in the manufacturing, packaging, labeling, or holding of dietary supplements use safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials when the light bulbs, fixtures, skylights, or other glass or glass-like materials are suspended over exposed components or dietary supplements in any step of preparation, unless your physical plant is otherwise constructed in a manner that will protect against contamination of components or dietary supplements in case of breakage of glass or glass-like materials.

We did not receive any comments specific to proposed § 111.20(f). On our own initiative, we are making clarifying changes to final § 111.20(f) by:

• Adding ''or glass-like materials'' after the word ''glass.'' Although proposed § 111.20(f) only specified glass, its intent was to cover any material that could shatter and contaminate components, dietary supplements, or contact surfaces. Therefore, we are adding glass-like material to final § 111.20(f) to cover fixtures and skylights that use non-glass materials (such as acrylic and polycarbonate materials) but could still contaminate components, dietary supplements, or contact surfaces if shattered or broken.

Further, we are stating that the requirement applies when the light bulbs, fixtures, skylights, or other glass or glass-like materials are suspended over exposed components or dietary supplements in any step of preparation. We made this change to prevent the rule from being misinterpreted as requiring firms to suspend light bulbs, fixtures, skylights, or other glass over components or dietary supplements in every step of preparation.

6. Final § 111.20(g)

Final § 111.20(g) (proposed § 111.20(g)) requires that any physical plant you use in the manufacturing, packaging, labeling, or holding of dietary supplements provide effective protection against contamination of components and dietary supplements in bulk fermentation vessels. Such protection includes: (1) Use of protective coverings; (2) placement in areas where you can eliminate harborages for pests over and around the vessels; (3) placement in areas where you can check regularly for pests, pest infestation, filth or any other extraneous materials; and (4) use of skimming equipment.

We did not receive comments specific to proposed § 111.20(g). We have made nonsubstantive, grammatical changes to the provision by replacing ''by any effective means'' with ''effective'' before the word protection and ''including consideration of'' with ''by, for example:''.

7. Final § 111.20(h)

Final § 111.20(h) (proposed § 111.20(h)) requires that any physical plant you use in the manufacturing, packaging, labeling, or holding of dietary supplements use adequate screening or other protection against pests, where necessary.

(Comment 105) One comment argues that proposed § 111.20(h) should be deleted because it is redundant when compared to proposed § 111.15(c) which would require you to not allow animals or pests in any area of your physical plant, except for guard or guide dogs in certain circumstances.

(Response) We disagree that final § 111.20(h) is redundant to proposed § 111.15(c) (final § 111.15(d)). Although both paragraphs deal with pests, final § 111.20(h) establishes a design requirement (i.e., a specific requirement to use adequate screening or other protection), while final § 111.15(d) sets forth a sanitation requirement (i.e., to not allow animals or pests in your physical plant). Therefore, we are retaining § 111.20(h) in the final rule.

G. Under This Subpart, What Records Must You Make and Keep? (Final § 111.23)

Final § 111.23(a) requires you to make and keep records required under this subpart in accordance with subpart P.

Final § 111.23(b) requires that you make and keep records of the written procedures for cleaning the physical plant and for pest control. This provision was added to ensure that the written procedures now required under final § 111.16 are maintained as required under subpart P.

Final § 111.23(c)(1) (proposed § 111.15(d)(3)) requires that you make and keep records that water, when used in a manner such that the water may become a component of the dietary supplement, meets the requirements of final § 111.15(e)(2).

(Comment 106) Several comments state there is no documentation requirement for water in the food or drug CGMPs. The comments, therefore, say there should be not be such a requirement in this final rule for dietary supplements.

(Response) To the extent that the comments assert we cannot include such a requirement for documentation in the dietary supplement CGMP because there is no corollary requirement in part 110, we have responded to this issue in section V of this document. The absence of a provision in drug CGMP requirements does not preclude us from requiring it in this final rule establishing CGMP requirements for dietary supplements for which we have no pre-approval scheme for ingredients used in such a product.

(Comment 107) Several comments ask us to clarify that, if a municipal water supply is used in a facility, the municipal water report is acceptable documentation of water quality. These comments say that a city's yearly report of its municipal water quality should be sufficient documentation, and that independent testing should not be required. Several comments claim that our officials made statements to this effect during a public meeting held on May 6, 2003.

The comments also assert that water quality in a community is typically well known due to public notification that is required by the Environmental Protection Agency or due to other resources. These comments say that municipal water supplies are also well controlled as a result of Environmental Protection Agency regulations, and that, if water quality in a community or country is suspect, we can move aggressively to enforce the standards. The comments argue that, overall, our enforcement burden would be less than requiring every company in the industry to maintain and produce documentation related to water quality.

(Response) A yearly municipal report is a good starting point for documenting water meets the requirements of final § 111.15(e), however, such a report cannot stand on its own as the only assurance that the water of the regulated body (such as persons subject to this final rule) complies with these regulations. A municipal water report offers reasonable assurance that the water entering your plant satisfies the requirements of the Environmental Protection Agency's NPDW regulations. However, as discussed previously, the requirement to show that the water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface, meets the requirements of § 111.15(e)(2), applies to water at the point of use, i.e., after it has passed through your plumbing system.

If you use a municipal water supply, you should take steps to ensure that you are at all times aware of problems, such as an acute problem with microbial contamination or a long-term problem associated with lead pipes that are present in some parts of the city water

supply, that may not be reflected in the municipal water report.

IX. Comments on Requirements Related to Equipment and Utensils (Subpart D)

A. Organization of Final Subpart D

Proposed subpart D contained two provisions regarding equipment, utensils, and automatic, mechanical, or electronic equipment. Table 5 of this document lists the sections in the final rule and identifies the corresponding sections in the 2003 CGMP Proposal that form the basis of the final rule.

TABLE 5.—DERIVATION OF SECTIONS IN SUBPART D

Final Rule	2003 CGMP Proposal
§ 111.25 What are the requirements under this subpart D for written procedures?	§ 111.25(c)(1) § 111.25(e)(1)
§ 111.27 What requirements apply to the equipment and utensils that you use?	§ 111.25(a), (b), (d), and (e)
§ 111.30 What requirements apply to automated, mechanical, or electronic equipment?	§ 111.30
§ 111.35 Under this subpart D, what records must you make and keep?	§§ 111.25(c)(1), (c)(2), (d), and (f), § 111.30(b)(2), (b)(5), and (c) § 111.50(c)(4)

B. Highlights of Changes to the Proposed Requirements for Equipment and Utensils

1. Revisions

The final rule includes revisions that reflect the final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.

2. Revisions Associated With the Reorganization

The revisions associated with the reorganization include:

- Renumbering proposed § 111.25 as final § 111.27 and correcting the numbering of the sections misnumbered in the 2003 CGMP Proposal;
- Requiring documentation and backup files in a separate section for recordkeeping requirements; and
- A nonsubstantive editorial change to refer to ''automated equipment'' rather than ''automatic equipment.'' Although there is no practical difference between these two terms, the term ''automated'' is the customary term.

3. Changes After Considering Comments

The final rule:

- Requires you to establish and follow written procedures to fulfill the requirements of subpart D, including written procedures for:
  - Calibrating instruments and controls;
  - Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and
  - Maintaining, cleaning, and sanitizing, as necessary, equipment, utensils, and other contact surfaces;
- Requires you to keep records of the maintenance, cleaning, and sanitizing of equipment either in equipment logs or in batch records;
- Requires that quality control personnel periodically review records of calibrations, inspections, or checks of automated, mechanical, or electronic equipment rather than approve such records when they are made;
- Specifies that software for a computer controlled process is included under automated, mechanical, or electronic equipment; and
- Clarifies that the requirement to retain backup files of software programs and of data entered into computer systems is for computer systems that you use in the manufacture, packaging, labeling, or holding of dietary supplements.

C. General Comments on Proposed Subpart D

(Comment 108) Some comments claim one or more proposed requirements are unconstitutionally vague under the Fifth Amendment and arbitrary and capricious under § 706(2)(B) of the APA. These proposed requirements include:

- § 111.25(a)(1), which would require that equipment and utensils be ''of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained''; and
- § 111.25(a)(2), which would require you to ''use equipment and utensils of appropriate design and construction so that use will not result in the contamination of components, dietary ingredients, or dietary supplements.''

In general, these comments assert the proposed sections did not define terms or phrases (such as ''suitable'' or ''appropriate design'') in a way that persons who are subject to the rule can discern the meaning of the term. These comments also assert the proposed sections do not limit enforcement officers' exercise of their discretion as to what will satisfy the requirements and, thus, invite exercise of unbridled discretion and disparate decisionmaking.

(Response) As discussed in section V of this document, we disagree that the terms are unconstitutionally vague, need to be defined, may result in discriminatory enforcement, or violate the APA. There has been sufficient usage of these terms in the food industry to enable manufacturers, and those who enforce the requirements, to comprehend and apply such terms. Agencies are permitted to use qualifying terms to enable them to address a wide variety of conditions at companies.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.25)

We received many comments that recommend written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to comments on specific provisions in the same section. We are adding final § 111.25 that requires you to establish and follow written procedures for certain requirements.

E. What Requirements Apply to the Equipment and Utensils That You Use? (Final § 111.27)

Final § 111.27 (proposed § 111.25) sets forth various requirements for equipment and utensils.

1. Final § 111.27(a)

a. *Final § 111.27(a).* Final § 111.27(a) (proposed § 111.25(a)(1)) requires you to use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained. In order to correct the misnumbering of this provision in the 2003 CGMP Proposal, this general requirement has been broken out from the remaining requirements of final § 111.27(a).

Final § 111.27(a)(1)(i) through (a)(1)(v) provide examples of such equipment, such as equipment used to hold or convey (§ 111.27(a)(1)(i)), equipment using compressed air or gas (§ 111.27(a)(1)(iii)), and equipment used in automated, mechanical, or electronic systems (§ 111.27(a)(1)(v)).

Final § 111.27(a)(1) is similar to proposed § 111.25(a)(1) except for two, nonsubstantive editorial changes. The first change replaces ''automatic equipment'' with ''automated equipment'' in what is now § 111.27(a)(1)(v) (proposed § 111.25(a)(1)(5)). Although there is no practical difference between

''automatic'' and ''automated,'' the latter is the customary term.

(Comment 109) Some comments argue that the proposal's use of terms such as ''appropriate design, construction, and workmanship to enable them to be suitable for their intended use'' and ''adequately cleaned and properly maintained'' are unconstitutionally vague under the Fifth Amendment and arbitrary and capricious under the APA.

(Response) We discuss those comments generally in section V of this document and, because we disagree that the final rule violates either the Fifth Amendment of the Constitution or the APA, we have not revised § 111.27(a)(1) except for the changes mentioned in the previous paragraphs.

b. *Final § 111.27(a)(2).* Final § 111.27(a)(2) (proposed § 111.25(a)(2)) requires you to use equipment and utensils of appropriate design and construction so that use will not result in the contamination of components or dietary supplements with: (1) Lubricants, (2) fuel, (3) coolants, (4) metal or glass fragments, (5) filth or any other extraneous material, (6) contaminated water, or (7) any other contaminants.

(Comment 110) Several comments state we should recognize that lubricants are an integral part of the encapsulation of gelatin-enrobed products and other dosage forms. These comments state lubricants are not potential contaminants, and in fact, help move gelatin ribbons through encapsulating machines. The comments would revise proposed § 111.25(a)(2) to read, ''lubricants not intended for product contact,'' to clarify the rule's intent.

(Response) We decline to revise the final rule as suggested by the comments. Final § 111.27(a)(2) states that the use of equipment and utensils must not result in the contamination of components or dietary supplements with lubricants. If a lubricant used for encapsulation does not result in contamination of the components or dietary supplements then the encapsulating machine complies with final § 111.27(a)(2).

c. *Final § 111.27(a)(3).* Final § 111.27(a)(3) (proposed § 111.25(a)(3)) requires all equipment and utensils you use to be: (1) Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces; (2) corrosion-resistant if the equipment or utensils contact components or dietary supplements; (3) made of nontoxic materials; (4) designed and constructed to withstand the environment in which they are used, the action of components or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and (5) maintained to protect components and dietary supplements from being contaminated by any source.

We did not receive comments specific to proposed § 111.25(a)(3). We have substituted the phrase ''in which they are used'' for ''of their intended use'' to make clear the requirement applies to equipment actually used in the manufacture, packaging, labeling, or holding of dietary supplements.

d. *Final § 111.27(a)(4).* Final § 111.27(a)(4) (proposed § 111.25(a)(4)) requires that the equipment and utensils you use have seams that are smoothly bonded or maintained to minimize accumulation of dirt, filth, organic material, particles of components or dietary supplements, or any other extraneous materials or contaminants. Final § 111.27(a)(4) is similar to proposed § 111.25(a)(4) and is analogous to § 110.40(b) which requires that seams on food-contact surfaces be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms. We have deleted the phrase ''to minimize the opportunity for growth of microorganisms'' as unnecessary in this context as the remaining wording of the provision encompasses this concept. In nonsubstantive editorial changes to final § 111.27(a)(4) we substitute ''particles of components or dietary supplements'' for ''component or dietary supplement particles'' to improve clarity, and re-order the list of extraneous materials or contaminants.

(Comment 111) Several comments argue that proposed § 111.25(a)(4) is overly restrictive by requiring equipment and utensils to ''have seams that are smoothly bonded or maintained'' to minimize contamination. The comments would revise the rule as follows: ''Equipment and utensils you use must be of proper design and maintained to minimize accumulation * * *.''

(Response) We disagree that proposed § 111.25(a)(4) (final § 111.27(a)(4)) is overly restrictive or that it requires a particular design. Final § 111.27(a)(4) requires seams that are smoothly bonded or maintained to minimize accumulation of dirt and gives firms the flexibility to use any design they choose, provided that the seams, by design or maintenance, minimize accumulation of contaminants.

e. *Final § 111.27(a)(5).* Final § 111.27(a)(5) (proposed § 111.27(a)(5)) requires that each freezer, refrigerator, and other cold storage compartment you use to hold components or dietary supplements: (1) Be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that indicates, and records, or allows for recording by hand, the temperature accurately within the compartment and (2) have an automated device for regulating temperature or an automated alarm system to indicate a significant temperature change in a manual operation.

(Comment 112) The preamble to the 2003 CGMP Proposal invited comment as to whether we should require specific target temperatures for dietary ingredients or dietary supplements held in freezers or cold storage (68 FR 12157 at 12190). Several comments assert there is no need for us to specify storage temperatures for dietary ingredients or dietary supplements. The comments state most dietary supplements and dietary ingredients are shelf stable based on their low water activity control, which limits and slows chemical degradation and microbiological growth. Other comments say target temperatures are not required where freezing is used only to enhance the milling properties (fracturing) of dried botanicals and not to prevent microbial contamination.

(Response) We have not included any specific target temperature requirements in the final rule. Consequently, firms should determine for themselves what temperatures are needed to ensure that the their dietary supplements are not adulterated (see final § 111.70 regarding the specifications you must establish).

f. *Final § 111.27(a)(6).* Final § 111.27(a)(6) (proposed § 111.25(a)(6)) requires the instruments or controls you use in the manufacturing, packaging, labeling, or holding of a dietary supplement, and instruments or controls that you use to measure, regulate, or record temperatures, pH, a_w, or other conditions, to control or prevent the growth of microorganisms or other contamination, be accurate and precise, adequately maintained, and adequate in number for their designated uses.

(Comment 113) One comment states that proposed § 111.25(a)(6)(i)'s requirements that instruments and controls be ''accurate and precise'' goes beyond ''typical'' calibration, and would require full validation of all instruments and controls. The comment argues that it is unnecessary to require both accuracy and precision for all instruments and controls, and would require precision only when necessary to prevent contamination. The comment states calibration to ensure accuracy of instruments and controls is usually sufficient to ensure control or prevention of the growth of

microorganisms or other contaminants in most situations. The comment gives an example where thermometers are used to monitor temperature in a warehouse where dietary supplements are stored.

(Response) We disagree that proposed § 111.27(a)(6) requires full validation of all equipment and controls. As discussed in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12190), accuracy means that the recorded measurements are equal to the (true value) of the thing being measured and precision means that individual measurements should be close to each other when made under the same conditions.

We also disagree that instruments need not be precise. An instrument that gives widely varying readings from one use to the next cannot ensure product quality over time. The degree of accuracy and precision is determined by the nature of the instrument or control and the process to which it relates. We have, however, made several nonsubstantive, editorial changes to § 111.27(a)(6) as well as other edits to conform to changes made throughout the final rule. These are the nonsubstantive editorial changes:

- Inserting a hyphen between ''hydrogen'' and ''ion'' and
- Revising the end of the paragraph so that it discusses ''instruments and controls that you use * * * to control or prevent the growth of microorganisms or other contamination * * *.'' The proposal stated ''instruments and controls that you use * * * that control or prevent the growth of microorganisms or other contamination * * *''. (In other words, the final rule replaces ''that'' with ''to''.)

g. *Final § 111.27(a)(7).* Final § 111.27(a)(7) (proposed § 111.25(a)(7)) requires that the compressed air or other gases you introduce mechanically into or onto a component, dietary supplement, or contact surface or you use to clean any contact surface be treated in such a way that the component, dietary supplement, or contact surface is not contaminated.

We received no comments specific to proposed § 111.25(a)(7).

2. Final § 111.27(b)

Final § 111.27(b) (proposed § 111.25(b)(1)) requires you to calibrate instruments and controls that you use in manufacturing or testing a component or dietary supplement. In order to correct the misnumbering of this provision in the 2003 CGMP Proposal, this general requirement has been broken out from the remaining requirements of final § 111.27(b) and now has paragraphs (b) and (b)(1) through (b)(3).

Final § 111.27(b)(1) through (b)(3) (proposed § 111.25(b)(1) and (b)(2)) requires you to calibrate before first use, and at the frequency specified in writing by the manufacturer of the instrument or control, or at routine intervals, or as otherwise necessary to ensure the accuracy and precision of the instrument and control.

(Comment 114) Several comments object to the level of detail regarding the proposed calibration. Specifically, the comments object to requiring that manufacturers calibrate instruments and controls ''as specified in writing by the manufacturer of the instrument and control.'' The comments say this requirement is more prescriptive than drug CGMP requirements. The comments acknowledge that following manufacturer specifications is likely to be part of the calibration procedure, but state that firms should have the flexibility to modify their procedures as necessary. These comments would couple proposed § 111.25(b) with a requirement to establish and follow written procedures for calibrating instruments and controls and redraft proposed § 111.25(b) to mirror the drug CGMP requirements, using language such as ''You must routinely calibrate instruments and controls that control or monitor critical parameters that you use in manufacturing or testing a component or dietary supplement.''

(Response) We disagree that proposed § 111.25(b) is overly prescriptive, exceeds drug CGMP requirements, or requires what is claimed by the comments. We discuss, generally, the issue of whether this final rule ''exceeds drug CGMPs'' in section V of this document. It is standard practice to calibrate an instrument before using it for the first time. A requirement that you calibrate as specified by the manufacturer of the equipment, or at routine intervals, or as otherwise necessary to ensure the accuracy and precision of the instrument and control, provides ample flexibility. Calibration, whether for instruments and controls used in manufacturing or testing drugs, devices, conventional foods, or dietary supplements, helps ensure the accuracy and precision of the instrument and control. We do not prescribe how frequently such calibration must be done, but it must be done often enough to ensure that instruments and controls are operating within the correct parameters. We are revising the 2003 CGMP Proposal (at § 111.27(b)(2)) to clarify that the requirement relates to the frequency of calibration.

(Comment 115) Several comments claim requirements relating to calibration of instruments and controls should be limited to those instruments and controls that directly affect the identity, purity, quality, strength, and composition of a dietary supplement. According to the comments, in most manufacturing facilities, there are many instruments and controls that do not directly affect identity, purity, quality, strength, and composition, and that calibrating all instruments and controls could easily become unduly burdensome. The comments also would limit the requirement for periodic calibration of instruments and controls to those instruments and controls directly involved in the critical control parameters of the process, i.e., those parameters needed to meet specifications or to ensure identity, purity, quality, strength, and composition. The comments suggest that critical control parameters would have to be established.

(Response) We decline to revise the rule as suggested by the comments. The requirement to calibrate instruments and controls is limited to those instruments and controls that you use in testing a component or dietary supplement or in manufacturing a dietary supplement. Any such equipment has the potential to affect, directly or indirectly, the quality of the dietary supplement.

(Comment 116) Some comments would revise proposed § 111.25(b)(1) to state that ''calibration should be done, where standards are available or where it is necessary to meet product specifications.''

(Response) We decline to revise the rule as suggested by the comments. It would be customary for an equipment manufacturer to have standards that can be used to calibrate the equipment, irrespective of the specific composition of the dietary supplement that is manufactured using that equipment. Equipment that is not or cannot be calibrated is unlikely to be in compliance with the requirement of final § 111.27(a)(6)(i) which requires instruments used in the manufacturing, packaging, labeling, and holding of dietary supplements, and instruments and controls that you use to perform certain operations, be accurate and precise.

(Comment 117) Some comments would revise proposed § 111.25 from the active voice to the passive voice. These comments claim that the active voice—i.e., requiring that ''you'' calibrate instruments and controls—requires that the dietary supplement manufacturer perform the calibration,

when in fact such calibrations are often performed by an outside service.

(Response) You may use an outside service. We would not consider that calibration done for you by an outside service is any different than calibration done by your employees, and it is you (rather than an outside service) whom we will hold responsible to ensure that the calibration is performed. Accordingly, we decline to revise the provisions as suggested.

(Comment 118) Several comments say calibration before first use should not be required for certified, precalibrated instrumentation. The comments state precalibrated instrumentation is much more expensive than noncalibrated instrumentation, with the additional expense attributed to the precalibration. Several comments would revise proposed § 111.25(b)(2) to read, ''you must calibrate, or be able to verify that the calibration has been completed, before first use,'' instead of ''you must calibrate before first use.'' The comments state that performance test results could be made available for this verification.

(Response) As written, the requirement that equipment be calibrated before first use includes calibration performed by a third party as a precalibration because we would consider that calibration performed by a third party as no different from calibration performed by one of your own employees. Under final § 111.35(b)(3) you must have documentation of the calibration.

If you purchase a precalibrated instrument, we strongly recommend that the vendor conduct the certification onsite after installation. If not, we strongly recommend that you verify that the instrument remains calibrated after it has been installed.

(Comment 119) Several comments ask whether the proposed requirement to calibrate ''before first use'' refers to the first use after installation or the first use after each start-up.

(Response) Final § 111.27(b)(1) refers to the first use after installation and does not require calibration after each start-up.

(Comment 120) Some comments would require that instruments and controls be calibrated, but argue that the final rule should not include detailed procedures specifying calibration methods. The comments said the rule should stay focused on end results and not process.

(Response) We disagree that the regulations should not focus on process. The essence of the CGMP requirements established by these regulations is a production and process control system, i.e., a process, that is designed to ensure the quality of the dietary supplement. The final rule gives firms the flexibility to use different calibration methods as long as the method used is established in a written procedure.

3. Final § 111.27(c)

Final § 111.27(c) (proposed § 111.25(d)) requires that you repair or replace instruments or controls that cannot be adjusted to agree with the reference standard.

We received no comments specific to proposed § 111.25(d).

4. Final § 111.27(d)

Final § 111.27(d) (proposed § 111.25(e)) requires you to maintain, clean, and sanitize, as necessary, all equipment, utensils, and any other contact surfaces used to manufacture, package, label, or hold components or dietary supplements. In order to correct the misnumbering of this provision in the 2003 CGMP Proposal, this general requirement has been broken out from the remaining requirements of final § 111.27(d) and now has paragraphs (d) and (d)(1) through (d)(7).

a. *Final § 111.27(d)(1).* Final § 111.27(d)(1) requires that the equipment and utensils be taken apart as necessary for thorough maintenance, cleaning, and sanitizing.

(Comment 121) Some comments argue that individual manufacturing operations will determine when sanitizing agents are needed after cleaning because of the wide variety of processes in the industry. The comments also say widespread use of sanitizing agents is creating resistant microbial strains, and incorporating unnecessary sanitization processes would contribute to this health concern.

Some comments recommend manufacturers calibrate sanitizing procedures to the particular process in a declared fashion depending upon the risk factors of their process and materials. The comments set out several standards for sanitation procedures.

(Response) Final § 111.27(d) requires you to maintain, clean, and sanitize, as necessary, equipment, utensils, and any other contact surfaces, used to manufacture, package, label, or hold dietary supplements. The final rule thus gives you discretion to decide when sanitizers or sanitizing treatments, such as heat, are necessary and does not mandate the incorporation of unnecessary sanitization processes.

Additionally, under final § 111.27(d) you have flexibility to determine when sanitizing is appropriate and to sanitize only as necessary. We note that this flexibility was also present in proposed § 111.25(e)(1). Some comments suggested calibrating sanitation operations based on risk. The final rule largely leaves it up to firms to decide whether to sanitize or to just clean without sanitizing, based on the risks associated with the materials and process used. However, under final § 111.27(d)(3), if you use wet processing, if you determine that it is necessary to clean a contact surface, you must also sanitize that surface.

(Comment 122) Several comments state the final rule should include a requirement for validating cleaning procedures. The comments argue that testing requirements for finished dietary supplements might not test for certain contaminants that could arise as a result of cleaning. One comment asserts these potential contaminants would be discovered in a properly designed and executed cleaning validation protocol, and that including these written cleaning procedures in the final rule would help prevent adulteration and help ensure the identity, purity, quality, strength, and composition of dietary supplements.

(Response) We decline to require specific cleaning validation procedures in the final rule. Final § 111.27(d) and the requirements for written procedures under final § 111.25(c) are sufficient to ensure the use of cleaning procedures to ensure the quality of the dietary supplement.

b. *Final § 111.27(d)(2).* Final § 111.27(d)(2) (proposed § 111.25(e)(2)) requires you to ensure that all contact surfaces, used for manufacturing or holding low-moisture components or dietary supplements, are in a dry and sanitary condition when in use. When the surfaces are wet-cleaned, you must sanitize them, when necessary, and allow them to dry thoroughly before you use them again.

We received no comments specific to proposed § 111.25(e)(2). We have substituted the phrase ''when in use'' for ''at the time of use'' for clarity.

c. *Final § 111.27(d)(3).* Final § 111.27(d)(3) (proposed § 111.25(e)(3)) requires you, if you use wet processing during manufacturing, to clean and sanitize all contact surfaces, as necessary, to protect against the introduction of microorganisms into components or dietary supplements. Final § 111.27(d)(3) also requires that:

- When cleaning and sanitizing is necessary, you clean and sanitize all contact surfaces before use and after any interruption during which the contact surface may become contaminated and
- If you use contact surfaces in a continuous production operation or in consecutive operations involving

different batches of the same dietary supplement, you must adequately clean and sanitize the contact surfaces, as necessary. In this provision, we substituted ''consecutive'' for ''back-to-back,'' a nonsubstantive change. We also inserted ''adequately'' to make clear that cleaning and sanitizing must be adequate.

(Comment 123) Several comments argue against using the term ''sanitize'' in proposed § 111.25(e)(3). The comments state that, based on the proposed definition of ''sanitize,'' § 111.25(e)(3) would require evaluation of any sanitation steps to ensure that the level of log reduction is reached, for example, by taking ''before and after'' swab samples. The comments would revise proposed § 111.25(e)(3) to state that equipment, utensils, etc. shall be cleaned and sanitized in a manner that keeps microorganisms and other adulterants from contaminating all components, ingredients, in-process materials, and finished goods.

(Response) The final rule now defines ''sanitize'' as ''to adequately treat cleaned equipment, containers, utensils, or any other cleaned product contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.'' The definition no longer specifies a level of log reduction, so the revised definition should eliminate the comments' concern as to any possible need for ''before and after'' samples.

d. *Final § 111.27(d)(4).* Final § 111.27(d)(4) (proposed § 111.25(e)(4)) requires you to clean surfaces that do not come into direct contact with components or dietary supplements as frequently as necessary to protect against contamination. Final § 111.27(d)(4) relates to final § 111.27(d)(2) and (d)(3). For example, you would not have to clean your ceilings as often as you clean your contact surfaces because your ceilings normally do not touch components or dietary supplements. However, you would have to clean your ceilings as frequently as necessary to prevent dust or other contaminants from falling onto your components, dietary supplements, and contact surfaces.

We received no comments specific to proposed § 111.25(e)(4). We substituted ''do not come into direct contact with'' for ''do not touch'' as a nonsubstantive editorial revision.

e. *Final § 111.27(d)(5).* Final § 111.27(d)(5) (proposed § 111.25(e)(5)) requires that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) be: (1) Stored in appropriate containers and (2) handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary supplements, or any contact surface.

We received no comments specific to proposed § 111.25(e)(5).

f. *Final § 111.27(d)(6).* Final § 111.27(d)(6) (proposed § 111.25(e)(6)) requires your cleaning compounds and sanitizing agents to be adequate for their intended use and safe under their conditions of use.

(Comment 124) One comment would delete proposed § 111.25(e)(6), stating it is redundant to proposed § 111.15(b), which would require you to use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and safe and adequate under the conditions of use.

(Response) We disagree with this comment. Proposed §§ 111.15(b)(1) and 111.25(e)(6) (now final §§ 111.15(b)(1) and 111.27(d)(6), respectively) differed in their requirements and their applicability. Proposed § 111.15(b)(1) would apply to cleaning compounds and sanitizing agents used in the physical plant and would require them to be ''safe and adequate under the conditions of use.'' In contrast, proposed § 111.25(e)(6) would apply to cleaning compounds and sanitizing agents used on equipment, utensils, and contact surfaces used to manufacture, package, or hold components, dietary ingredients, or dietary supplements, and it would require such cleaning compounds or sanitizing agents to be ''adequate for intended use and safe under condition [sic] of use.'' By using the phrase ''adequate for intended use,'' proposed § 111.25(e)(6) would have you consider whether a particular cleaning compound or sanitizing agent was appropriate for the particular use to which it was being applied.

Furthermore, depending on the situation, a cleaning compound or sanitizing agent that is appropriate for use on a physical plant may be inappropriate for use on equipment, utensils, and contact surfaces. For example, a powdered cleaning compound might be suitable for cleaning your physical plant's floors, but inappropriate for cleaning equipment that mixes components. In other words, the ''conditions of use'' can also vary between final §§ 111.15(e)(1) and 111.27(d)(6) and lead to different conclusions regarding use of the same cleaning compound.

Additionally, on our own initiative, we have made two editorial, nonsubstantive changes to final § 111.27(d)(6). The final rule now states that the cleaning compounds and sanitizing agents must be adequate for ''their'' intended use and safe under ''their conditions'' of use.

g. *Final § 111.27(d)(7).* Final § 111.27(d)(7) (proposed § 111.25(e)(7)) requires you to store cleaned and sanitized portable equipment and utensils that have contact surfaces in a location and in a manner that protects them from contamination. We received no comments specific to proposed § 111.25(e)(7).

F. Reorganization of Certain Paragraphs in Proposed § 111.25

Proposed § 111.25 would impose certain requirements relating to written procedures for calibrating instruments and controls (proposed § 111.25(c) and (d)) and keeping calibration records (proposed § 111.25(f)). The final rule now contains a new recordkeeping section (§ 111.35) that combines elements of proposed § 111.25(c), (d), and (f), as well as other sections. We discuss comments on proposed § 111.25(c), (d), and (f) and describe final § 111.35 in this section.

G. What Requirements Apply to Automated, Mechanical, or Electronic Equipment? (Final § 111.30)

Final § 111.30 sets forth requirements for automated, mechanical, or electronic equipment that you use to manufacture, package, label, or hold a dietary supplement.

1. Comments on the Organization and Framework of Proposed § 111.30

(Comment 125) Some comments would revise proposed § 111.30(a) to replace ''equipment to manufacture, package, label, and hold'' with ''equipment to manufacture, package, label, or hold.'' The comments said that the same piece of equipment will not serve to manufacture, package, label, and hold components or dietary supplements.

(Response) We agree, and have revised § 111.30 accordingly. Final § 111.30 also contains the following changes:

- ''Automatic'' (as in ''automatic equipment'') is replaced with ''automated'' as an editorial, nonsubstantive change;
- The phrase ''determine the suitability of your equipment'' has been revised to read ''determine the suitability of the equipment * * *'' in § 111.30(b) and has no substantive impact; and

• We have substituted the word ''met'' for ''achieved'' to comply with ''plain language'' initiatives and to be consistent with other provisions.

We describe other changes to proposed § 111.30 in the following paragraphs.

(Comment 126) Several comments support proposed § 111.30 particularly with respect to computers. The comments state computers are susceptible to erroneous data input, are subject to malfunctions and software problems, and thus should be regulated under the final rule.

One comment questions why we organized proposed § 111.30 into two paragraphs (a) and (b). The comment claims there was no meaningful difference between the two paragraphs.

Other comments say some proposed requirements for automatic, mechanical, and electronic equipment, such as the proposed requirement for maintaining backup files of data entered into computer systems, would apply to automatic, mechanical, and electronic equipment that are not related to CGMPs. The comments argue that proposed § 111.30(b) would apply to computers on which payroll records are maintained, and that such a requirement does not belong in these CGMPs.

(Response) We agree, in part, and disagree, in part, with the comments. We agree that computers used in the manufacture, packaging, labeling, or holding of dietary supplements should be, and are, subject to final § 111.30.

We disagree, however, with those comments that interpreted proposed § 111.30(a) and (b) as being the same or interpreted proposed § 111.30 as applying to equipment that has no direct bearing on dietary supplements. Proposed § 111.30(a) differed from proposed § 111.30(b) in that paragraph (a) would pertain to the operation and suitability of your equipment within your manufacturing process. In contrast, proposed § 111.30(b) would apply to calibration of your equipment and controls you establish for your equipment.

We disagree with those comments that would interpret proposed § 111.30(b) as applying to payroll computers or other equipment that has no CGMP function. To prevent misinterpretations of final § 111.30, we have revised it to apply to equipment ''that you use to manufacture, package, label, or hold a dietary supplement'' and renumbered proposed § 111.30(a)(1), (a)(2), (b)(1), (b)(3), and (b)(4) as § 111.30(a) through (e), respectively. Proposed § 111.30(b)(2) which would require you to make and keep written records of equipment calibrations, inspections, and checks, and proposed § 111.30(b)(5) which would require you to make and keep backup files of software programs and data, are now incorporated into final § 111.35, and we discuss these provisions later in this section.

(Comment 127) Several comments would limit proposed § 111.30(a) and (b) to automatic, mechanical, or electronic equipment that actually affects product specifications. The comments argue that, in a modern manufacturing facility, most, if not all, equipment used to manufacture, package, label, or hold any food product is automatic, mechanical, or electronic. The comments say that equipment, such as forklifts, should not be required to be designed or selected in a manner that ensures that product specifications are met, as would be required in proposed § 111.30(a)(1), or to be calibrated, as would be required in § 111.30(b)(1).

(Response) As we stated previously, we have revised § 111.30 so that it applies to equipment ''that you use to manufacture, package, label, or hold a dietary supplement.'' This revision should prevent the rule from being interpreted as applying to forklifts or other equipment that have no bearing on the manufacture, packaging, labeling, or holding of dietary supplements.

(Comment 128) Several comments argue that proposed § 111.30 is redundant to proposed § 111.25 and could be removed without meaningful effect. One comment argues that proposed § 111.30(a) and (b) (i.e., that all automatic, mechanical, and electronic equipment be designed or selected to ensure that product specifications are consistently achieved and operate satisfactorily within operating limits required by the process) are redundant to proposed § 111.25(a)(1) (which would require that all equipment be of appropriate design, construction, and workmanship to enable them to be suitable for their intended use) and proposed § 111.25(a)(1)(v) (which would state that ''equipment'' includes automatic, mechanical, or electronic systems). The comment states that, for equipment to be suitable for its intended use, the equipment must operate satisfactorily within operating limits and, by extension, ensure that product specifications are consistently achieved. The comment states the separate regulations for automatic equipment in the drug CGMPs is less detailed despite our efforts to present the 2003 CGMP Proposal in ''simplified language.''

(Response) We disagree that proposed § 111.30 is redundant to proposed § 111.25 (final § 111.27). Although both proposed §§ 111.25 and 111.30 pertained to equipment, they differed in their focus. Proposed § 111.25 would focus on equipment design, construction, maintenance, cleaning, sanitizing, and calibration. In contrast, proposed § 111.30 would focus on the equipment's operation or suitability within your manufacturing process. For example, proposed § 111.30(a)(2) would require you to determine the suitability of your equipment by ensuring that your equipment is capable of operating satisfactorily ''within the operating limits required by the process.'' In contrast, proposed § 111.25 had no comparable suitability requirement insofar as your manufacturing processes were concerned. Thus, the proposed sections are not redundant, and the final rule retains both § 111.27 (proposed § 111.25) and § 111.30.

2. Comments Specific to Proposed § 111.30

a. *Final § 111.30(a) and (b).* Final § 111.30(a) (proposed § 111.30(a)(1)) requires you, for any automated, mechanical, or electronic equipment you use to manufacture, package, label, or hold a dietary supplement, to design or select the equipment to ensure that dietary supplement specifications are consistently met.

Final § 111.30(b) (proposed § 111.30 (a)(2)) requires you, for any automated, mechanical, or electronic equipment that you use to manufacture, package, label, or hold a dietary supplement, to determine the suitability of the equipment by ensuring that the equipment is capable of operating satisfactorily within the operating limits required by the process.

(Comment 129) Some comments argue that the requirements of proposed § 111.30(a) might be impossible to meet because, in many instances, dietary supplement manufacturers cannot predict, at the time of purchase, the entire range of ingredients and products for which a particular piece of equipment might be used. The comments argue that a particular piece of equipment's suitability for a particular ingredient or product must be evaluated at the time the need arises. The comments would revise proposed § 111.30(a)(1). The words ''Design and select equipment to ensure'' would be replaced with the words ''Use equipment that ensures;'' and proposed § 111.30(a)(2) would be revised to replace the words ''is capable of operating'' with the word, ''operates.''

(Response) We disagree with the comments. Although a company may not know the entire range of products that a machine may be used for,

proposed § 111.30(a)(1) and (a)(2) would neither require you to determine all uses of equipment at the time of purchase nor prevent you from evaluating an old machine for a new use (these provisions are renumbered as final § 111.30(a) and (b), respectively). Thus, even if you chose to use old equipment for a new use, you still must select that equipment to ensure that dietary supplement specifications are consistently met with the new equipment use and determine the suitability of the new equipment use by ensuring that the equipment is capable of operating satisfactorily within the operating limits required by the new process.

(Comment 130) Several comments express concern that facilities and much equipment in the industry are old and lack historical documentation. These comments ask us to clarify whether manufacturers would have to establish baseline information for old facilities and equipment.

(Response) All equipment that you use, regardless of whether it is old or new, must be capable of doing what you intend it to do. Just as you could evaluate old equipment for a new use, you can demonstrate that old equipment does, in fact, do what you intend it to do for uses that you developed before these CGMP requirements were established, and thereby comply with final § 111.30(a) and (b).

(Comment 131) Several comments argue that our statement in the preamble to the 2003 CGMP Proposal that ''systems need to be installed in a manner that takes into account the inherent limitations of the system, tested under conditions that reflect actual conditions of use'' (68 FR 12157 at 12193) is vague and subject to multiple interpretations.

(Response) We disagree with the comment. The statement in question should be read in context because the preamble to the 2003 CGMP Proposal described several conditions for consideration. The preamble to the 2003 CGMP Proposal stated, in relevant part: ''Some systems may work properly only within a narrow range of environmental conditions, such as temperature and humidity, and some might be particularly sensitive to electromagnetic interference. The actual conditions of use of a system should be considered as early as possible in its design and development. Systems need to be installed in a manner that takes into account the inherent limitations of each system, tested under conditions of use, and properly maintained to ensure that they continue to function as expected during their lifetime'' (68 FR 12157 at 12193.) Thus, suitability under final § 111.30(b) involves considerations of how the equipment would be affected by environmental conditions, whether the equipment is appropriate for its intended use, and whether the equipment can be maintained properly to ensure satisfactory operation.

(Comment 132) Several comments argue that the requirement of proposed § 111.30(a)(2) to ''determine the suitability of your equipment by ensuring that your equipment is capable of operating satisfactorily within the operating limits required by the process'' is vague and subject to many interpretations. These comments assert that this may cause an uneven playing field among companies as they apply differing standards to this requirement. The comments also argue that the vagueness of this requirement could potentially cause uneven enforcement, depending on the experience and understanding of individual inspectors.

(Response) We disagree that proposed § 111.30(a)(2) (final § 111.30(b)) is vague or may result in uneven enforcement. There has been sufficient common usage of terms such as ''suitable,'' ''capable,'' and ''satisfactorily'' in the industry to enable firms, and those who enforce the requirements, to comprehend and apply such terms to particular operations. Agencies may use qualifying terms to enable them to address a wide variety of conditions, and such terms provide the flexibility needed for various operations.

(Comment 133) Several comments assert that proposed § 111.30(a)(2) is without justification and overly prescriptive when compared to conventional food CGMPs.

(Response) As discussed in section V of this document, the mere fact that a dietary supplement CGMP requirement has no counterpart in the food CGMP regulations, or has more detail than a counterpart in such regulations, does not mean that it is overly prescriptive. Rather, what is important is whether proposed § 111.30(a)(2) (final § 111.30(b)) is necessary to ensure the quality of the dietary supplements. For example, the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12193) discussed how the incorporation of software into the operation of automatic equipment has both increased the complexity of such equipment and resulted in a process that may operate differently for each execution, because a software-based control system can be configured at will by the operator or by the system itself. Therefore, it is essential that you ensure that automated equipment is capable of operating satisfactorily within the operating limits required by the process.

(Comment 134) Several comments urge us to develop a separate guidance document with respect to determining the suitability and capability of equipment used in the manufacture of dietary supplements.

(Response) We believe that firms have sufficient experience to determine whether equipment is suitable and capable of performing its intended function. However, if we find that guidance will be helpful, we will consider whether to issue guidance at a later date.

b. *Final § 111.30(c).* Final § 111.30(c) (proposed § 111.30(b)(1)) requires you, for any automated, mechanical, or electronic equipment you use to manufacture, package, label, or hold a dietary supplement, to routinely calibrate, inspect, or check the equipment to ensure proper performance. Final § 111.30(c) also requires quality control personnel to periodically review these calibrations, inspections, or checks.

(Comment 135) Several comments claim the requirement for the quality control unit to approve calibrations, inspections, or checks of equipment is too prescriptive and that qualified persons outside of the quality control unit should be able to approve these calibrations, inspections, or checks. The comments also state the quality control unit should perform audits of the records generated to ensure the appropriate calibrations, inspections, or checks are being adequately performed at the required intervals.

Other comments refer to related requirements in proposed § 111.37(b)(8) that the quality control unit review all records for equipment calibrations, inspections, or checks. The comments state the requirements for oversight by the quality control unit in proposed § 111.37(b)(8) are excessive and go beyond requirements for both the drug CGMPs and food CGMPs. One comment would revise proposed § 111.37(b)(8) to require a review of all records when there is a negative impact on the dietary supplement due to a calibration failure.

(Response) Final § 111.12(b) requires that you identify who is responsible for your quality control operations, and each person who is designated to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations. Thus, you may identify any person whom you believe is qualified to approve calibrations, equipments, or checks to perform quality control operations.

We disagree that the review by quality control personnel should be limited to circumstances when there has been a calibration failure. One function of quality control personnel is to provide oversight to prevent problems with the product that you distribute by finding any problems with the equipment that you use to produce the product rather than to investigate the cause of a problem with a product that you already distributed. However, we agree that it is sufficient to periodically review the records of calibrations, inspections, or checks of automated, mechanical, or electronic equipment, for example, on an annual basis, rather than to approve each record when it is made. A periodic review can uncover trends in the performance of the equipment that have the potential to adversely affect the quality of the dietary supplement and that may not be obvious by merely approving each record when it is made. Seeing such trends would enable quality control personnel to recommend corrective actions. This periodic review is consistent with proposed § 111.37(b)(8) which would require the quality control unit to ''review'' all records for equipment calibration, inspections, or checks rather than ''approve'' these records. Therefore, we have revised the requirement that the quality control unit approve calibrations, inspections, or checks of automatic, mechanical or electronic equipment so that final § 111.30(c) requires that quality control personnel periodically review such operations rather than approve them when they are made.

Additionally, we have made a minor change to § 111.30(c). The change inserts the words ''the equipment'' after ''Routinely calibrate, inspect, or check * * *.'' This insertion simply reiterates that ''the equipment'' must be routinely calibrated, inspected, or checked.

c. *Final § 111.30(d).* Final § 111.30(d) (proposed § 111.30(b)(3)) requires you, for any automated, mechanical, or electronic equipment you use to manufacture, package, label, or hold a dietary supplement, to establish and use appropriate controls for the equipment (including software for a computer-controlled process) to ensure that any changes to the manufacturing, packaging, labeling, holding, or other operations are approved by quality control personnel and instituted only by authorized personnel.

(Comment 136) The preamble to the 2003 CGMP Proposal invited comment on whether we should regulate computerized systems separately from other automatic equipment, given the broad range in sophistication, complexity, and computerization in manufacturing equipment (68 FR 12157 at 12194).

Several comments state that computers are susceptible to erroneous data input and subject to malfunctions and software problems and, thus, should be regulated under the final rule.

(Response) We agree that computers used in the manufacturing processes should be regulated under the final rule. As the preamble to the 2003 CGMP Proposal stated the incorporation of software into the operation of automatic equipment has increased the complexity of such equipment and resulted in a process that may operate differently for each execution, because a software-based control system can be configured at will by the operator or by the system itself (68 FR 12157 at 12193). Additionally, final § 111.35(b)(5) requires you to make and keep backup files of software programs and data to keep them secure from alterations, inadvertent erasures, or loss. The issue in the preamble to the 2003 CGMP Proposal, however, was whether computerized systems should be regulated separately from other equipment; in the absence of comments supporting separate treatment for computerized systems, we have included computerized systems as ''equipment'' in final § 111.30(d).

We are, however, revising final § 111.30(d) in the following manner:

- We are inserting the words ''for automated, mechanical, and electronic equipment (including software for a computer controlled process)'' after ''Establish and use appropriate controls.'' This change simply reiterates the types of equipment for which appropriate controls must be established and used, and makes it clear that software is included under the rule and
- We are rephrasing the purpose of § 111.30(d). The proposal stated that you must establish and use appropriate controls ''to ensure that your quality control unit approves changes in the master manufacturing record batch control records, packaging operations, and label operations, or changes to other operations related to the equipment that you use and that only authorized personnel institute the changes.'' The final rule states that you must establish and use appropriate controls for your equipment ''to ensure that any changes to the manufacturing, packaging, labeling, holding, or other operations are approved by quality control personnel and instituted only by authorized personnel.''

As revised, final § 111.30(d) shifts its emphasis from the person(s) who must approve or institute the changes to the types of changes that must be approved and instituted. This shift in emphasis is appropriate given that the final rule addresses responsibilities of the quality control personnel elsewhere.

d. *Final § 111.30(e).* Final § 111.30(e) (proposed § 111.30(b)(4)) requires you, for any automated, mechanical, or electronic equipment you use to manufacture, package, label, or hold a dietary supplement, to establish and use appropriate controls to ensure that the equipment functions in accordance with its intended use. Quality control personnel must approve these controls.

We did not receive comments specific to proposed § 111.30(b)(4).

3. Reorganization of Certain Paragraphs in Proposed § 111.30

As we explained earlier in this section, proposed § 111.30 would impose certain requirements relating to written records of equipment calibrations, inspections, or checks (proposed § 111.30(b)(2)) and making and keeping backup files of software programs and data (proposed § 111.30(b)(5)). The final rule now contains a new recordkeeping section, final § 111.35, that combines elements of proposed § 111.30(b)(2) and (b)(5), as well as other sections.

Additionally, proposed § 111.30(c) would require you to keep records in accordance with the written procedure and recordkeeping requirements in proposed § 111.125. Section 111.35 of the final rule now incorporates proposed § 111.30(c) as well. We discuss final § 111.35 in the following paragraphs.

H. Under This Subpart, What Records Must You Make and Keep? (Final § 111.35)

Final § 111.35 describes the recordkeeping requirements. It represents a combination of proposed §§ 111.25(c)(1) through (c)(2), (d)(1) through (d)(7), and (f); 111.30(b)(2), (b)(5), and (c); and 111.50(c)(4).

1. Final § 111.35(a)

Final § 111.35(a) states that you must make and keep records required under subpart D in accordance with subpart P. Subpart P deals with records and recordkeeping.

Final § 111.35(a) is broader than proposed § 111.25(f), which stated that you ''must keep calibration records as required by this section in accordance with'' the 2003 CGMP Proposal's recordkeeping section, and compared to proposed § 111.30(c), which stated that you must keep ''automatic, mechanical, or electronic equipment records required by this section in accordance

with'' the 2003 CGMP Proposal's recordkeeping section. However, final § 111.35(a) has the same effect as proposed §§ 111.25(f) and 111.30(c).

We did not receive any substantive comments on proposed §§ 111.25(f) or 111.30(c).

2. Final 111.35(b)(1) and (b)(2)

Final § 111.35(b) combines the various recordkeeping requirements that were in proposed §§ 111.25(c) (written procedures for calibrating instruments and controls and documentation that those procedures were followed and that the calibration was performed), 111.25(d) (written procedures or documentation for calibration, such as the instrument or control calibrated and the calibration date), 111.30(b)(2) and (b)(5) (written records of equipment calibrations, inspections, or checks, and backup files of software and data, respectively), and 111.50(b)(4) (inclusion of date and time of maintenance, cleaning, and sanitizing of equipment and processing lines in the batch record).

Specifically, final § 111.35(b)(1) states that you must make and keep records of ''written procedures for fulfilling the requirements of this subpart,'' including written procedures for:

- Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement. This paragraph is similar to proposed § 111.25(c). Although we did not receive any substantive comment on proposed § 111.25(c), we are rephrasing the paragraph due to its reorganization as part of final § 111.35. Additionally, although proposed § 111.25(c) would require you to document that the written procedures for calibration were followed each time a calibration is performed, we are moving the documentation requirement to final § 111.35(b)(3) which we discuss later in this section.
- Calibrating, inspecting, and checking automated, mechanical, and electronic equipment. This paragraph is similar to proposed § 111.30(b)(2), although we are rephrasing the paragraph due to its reorganization as part of final § 111.35.
- Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements. This paragraph relates to final § 111.25(c) which requires you to establish and follow written procedures for such activities.

We did not receive any comments specific to proposed §§ 111.25(c) or 111.30(b)(2).

Final § 111.35(b)(2) (proposed § 111.50(c)(4)) requires you to make and keep documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment, unless such documentation is kept with the batch record.

(Comment 137) Proposed § 111.50(c)(4) would require that the batch record include the date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch. The preamble to the 2003 CGMP Proposal also invited comment on whether the person performing the maintenance, cleaning, and sanitizing of portable equipment and utensils should document at the time of performance the maintenance, cleaning, and sanitizing (68 FR 12157 at 12192[8]). Several comments argue that the final rule should require documentation at the time of performance of equipment, utensil, and contact surface maintenance, cleaning, and sanitation and should also require this documentation to be kept as records. The comments explain that such recordkeeping is common practice in the industry, is an important part of batch history, and omitting such a requirement would diminish the industry standard. In addition, the comments state that written records are an effective way to ensure that there is consistency in how employees are trained and to assess compliance.

Several comments agree that equipment maintenance, cleaning, and sanitizing records should be kept and state that this information should be kept with individual pieces of equipment, rather than in the batch record as proposed § 111.50(c)(4) would require. The comments say it is easier and more efficient for some companies to maintain equipment logs that can be referenced when necessary.

Other comments say manufacturers should have flexibility to design a recordkeeping program suited to their operations, and should have the option of using an equipment log as it provides an efficient way to document, trace, and review equipment use, maintenance, cleaning, and sanitization of equipment. According to these comments, because the 2003 CGMP Proposal would require batch production records to identify all equipment used during production, this will allow for cross-referencing with the equipment log, should the need occur. The comments argue that the proposed approach will be awkward for some companies to comply with and would not result in collection of information in a logical order or location where it can be easily referenced and reviewed, such as on the production floor, or to provide data for trend analysis. The comments also contend requiring all information to be maintained in the batch record will be difficult in practice and place an enormous burden on companies.

(Response) We agree that documenting the cleaning, sanitizing, and maintenance of equipment is important. However, we have revised the provision so that these records need not be part of the batch record. Instead, final § 111.35(b)(2) requires you to make and keep documentation of the date of use, maintenance, cleaning, and sanitizing of equipment in individual equipment logs, unless such documentation is kept with the batch record. By ''equipment log,'' we mean a written record that includes information about the history of a piece of equipment. This history includes items such as date of installation, routine maintenance, repairs, and cleaning.

Additionally, final § 111.260 requires you to identify the equipment and processing lines used in producing the batch and either provide a cross-reference that will make it possible to find the applicable equipment log as needed or include documentation that equipment was cleaned, sanitized, or maintained (we discuss final § 111.260 in section XIV of this document). For example, you may keep records documenting that you cleaned containers you will use for holding a finished batch either in records associated with the equipment you use for cleaning, or with the applicable batch record, depending on what is most convenient and practical for your operations.

(Comment 138) Several comments state documenting the cleaning of contact surfaces would be unnecessarily labor-intensive because the term is so broadly defined. Other comments argue that documenting the cleaning of utensils is unnecessary and inappropriate. These comments support requiring documentation for the cleaning of large equipment, but claim that requiring manufacturers to uniquely identify each spoon, spatula, container, and hose (or other general cleaning) in order to document each cleaning would be inappropriate and create an enormous burden on the manufacturer. According to these comments, such a requirement would slow and complicate the cleaning process, making proper cleaning more cumbersome. The comments assert that

[8]Although the preamble to the 2003 CGMP Proposal discussed this issue in relation to proposed § 111.25 (''What Requirements Apply to the Equipment and Utensils You Use?''), the same principle applies to proposed § 111.50(c)(4).

contamination from these sources has not caused any recalls and is not justified.

(Response) We disagree with these comments. The final rule requires you to document the work that was done, but gives you the flexibility to decide how to document that work was done. For contact surfaces such as containers you use to hold a finished batch, you could, for example, record the cleaning either on a single line that you provide in your batch record, or as a line entry in the log of the equipment that you use to clean the containers, or in some other way that suits your needs. These are not labor-intensive requirements.

It is important that you have procedures in place to know that small items, such as spatulas, are clean when you use them. For example, if you have a log where you designate equipment that has been cleaned, your batch record could simply have a place to check that you used equipment designated as clean.

3. Final § 111.35(b)(3)

Final § 111.35(b)(3) (proposed § 111.25(d)(1) through (d)(7)) requires you to make and keep documentation of any calibration, each time the calibration is performed, for instruments and controls that you use in manufacturing or testing a component or dietary supplement. In the documentation you must: (1) Identify the instrument or control calibrated; (2) provide the calibration date; (3) identify the reference standard used, including the certification of accuracy of the known reference standard and a history of recertification of accuracy; (4) identify the calibration method used, including appropriate limits for accuracy and precision of instruments and controls when calibrating; (5) provide the calibration reading or readings found; (6) identify the recalibration method used, and reading or readings found, if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and (7) include the initials of the person who performed the calibration and any recalibration.

(Comment 139) Some comments support proposed § 111.25(d). However, other comments argue that the documentation requirements are unduly prescriptive. Some comments would revise proposed § 111.25(d) to more closely mirror the requirements in drug CGMPs. Some comments suggest the requirement to maintain written records of calibrations should simply state ''You must maintain written records of calibrations according to Sec. 111.125.'' Other comments suggest detailed calibration requirements would not be needed if the final rule included requirements to establish and follow written procedures.

(Response) The information required under final § 111.35(b)(3) (proposed § 111.25(d)) is the minimum amount necessary to provide sufficient information concerning equipment calibration. For example, some firms may have more than one machine to perform a given function; in those situations, documentation that identified the exact machine that was calibrated would distinguish it from other, seemingly identical, but noncalibrated machines. Likewise, if the maintenance instructions for a machine called for calibration checks every month, documenting the date of calibration would show you whether calibrations were done on schedule. As another example, if a machine required calibration according to a particular standard, identifying the reference standard would help verify that the calibration was done correctly.

Thus, we disagree with those comments claiming that proposed § 111.25(d) was too prescriptive. If, for example, the final rule simply directed you to document calibration, without specifying what information should be contained in that documentation, then the resulting documentation could have little or no value. For example, assume that you have two identical pieces of equipment, but only one had been calibrated. If the documentation simply said, ''machine was calibrated,'' you would not know which machine had been calibrated. As another example, if you had a machine that had to be recalibrated every year, and the documentation merely said, ''recalibration completed,'' you would not know whether the machine had been recalibrated yesterday, last month, last year, or 4 years ago.

With respect to the argument that proposed § 111.25(d) should be revised to resemble the drug CGMPs, we disagree. We recognize that the drug CGMPs are less detailed with respect to documentation; for example, 21 CFR 211.68(a), ''Automatic, mechanical, and electronic equipment,'' simply states, in relevant part, ''If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance'' and ''Written records of those calibration checks and inspections shall be maintained.'' However, the comments overlook the fact that, from 1993 to 2003, the Center for Drug Evaluation and Research (CDER) issued periodic guidance, in the form of ''Human Drug CGMP Notes,'' and those guidances offered advice on various drug CGMP issues. With respect to calibration, for example, the December 1997 edition dealt with the question of whether the drug CGMP regulations require equipment to be labeled with calibration dates. The guidance identified various regulations that would be applicable and also said that: ''During an inspection a firm should be able to document when a specific piece of equipment was last calibrated/maintained, the results or action, and when its next calibration/maintenance is scheduled. The absence of such documentation is a CGMP deviation'' (see CDER, ''Human Drug CGMP Notes,'' December 1997, at page 3 (Ref. 29)).

This advice is comparable, in several respects, to the information required by final § 111.35(b)(3). For example, it refers to a ''specific piece of equipment,'' which is similar to final § 111.35(b)(3)(i)'s requirement to identify the instrument or control calibrated. It refers to the time when calibration occurred; this is similar to final § 111.35(b)(3)(ii)'s requirement to provide the calibration date. Although public distribution of ''Human Drug CGMP Notes'' ended in 2003, and the document was circulated only within FDA from 2001 to 2003 (but was available through FOIA), the guidances offered the drug industry advice on complying with the drug CGMPs, and we have retained the guidances on our Internet site. In other words, the drug CGMP regulations did not have to be as ''prescriptive'' because the drug industry learned about our interpretations or expectations of the drug CGMPs through guidance.

Here, in contrast, there is no comparable history of issuing periodic guidance to inform the dietary supplement industry about specific CGMP issues.

Yet, even if final § 111.35 is more ''prescriptive'' than the drug CGMPs, that difference does not mean that we must revise the rule to ''mirror'' the drug CGMPs. The dietary supplement industry is more diverse compared to the drug industry, and so, at least with respect to documenting calibration, more—rather than less—detail is appropriate.

We do note, however, that final § 111.35(b)(3) differs from proposed § 111.25(d) in the following respects:

- § 111.25(d) would require you to identify specific calibration-related information ''in any written procedure or at the time of performance,'' final § 111.35(b)(3) requires documentation ''each time the calibration is performed.'' Final section 111.35(b)(1)

requires you to have records of the written procedures for calibrating instruments and controls, but does not specify the contents of such written procedures;

- § 111.25(d) would refer to ''instruments and controls.'' Final § 111.35(b)(3) now refers to ''instruments and controls that you use in manufacturing or testing a component or dietary supplement.'' This change clarifies the instruments and controls that are subject to final § 111.35(b)(3) and is consistent with final § 111.27(b), which requires you to calibrate instruments and controls;
- The type of information that must be documented under § 111.35(b)(3)(i) through (b)(3)(vii) is essentially identical to that in proposed § 111.25(d)(1) through (d)(7), but we revised the sentence structure due to the manner in which we reorganized final § 111.35;
- § 111.25(d)(6) would have you identify the recalibration method used. Final § 111.35(b)(3)(vi) requires you to identify the recalibration method used ''and reading or readings found.'' The addition of ''reading or readings found'' is consistent with the remainder of proposed § 111.25(d)(6) (final § 111.35(b)(3)(vi)) which is a simplification of the phrase ''accuracy or precision or both accuracy and precision limits for instruments and controls were not met.'' One would only know that limits were not met based on a reading or readings; and
- § 111.25(d)(7) would require the initials of the person who performed the calibration. Final § 111.35(b)(3)(vii) requires the initials of the person who performed the calibration and any recalibration. Arguably, recalibration is a type of calibration, but we have added ''any recalibration'' to final § 111.35(b)(3)(vii) to ensure that recalibrations are included in the rule.

(Comment 140) Several comments would revise proposed § 111.25(d) to read, ''The following must be identified * * *'', rather than ''you must identify.'' The comments explain that calibrations and recalibrations are often performed by the equipment manufacturer, vendor, or other outside service, rather than by the dietary supplement manufacturer. The comments argue that the proposal requires that the calibration or recalibration must be performed onsite (i.e., at the plant manufacturing the dietary ingredient or supplement) when in fact many calibrations can, or even must, be performed offsite.

(Response) We decline to revise the paragraph as requested. As we discuss in section VI of this document, the term ''you'' can refer to someone with whom you contract, but you are responsible for ensuring that the calibration requirements are met, and to have documentation of the calibration, even though the steps may be performed offsite.

4. Final § 111.35(b)(4)

Final § 111.35(b)(4) (proposed § 111.30(b)(2)) requires you to make and keep written records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment that is used to manufacture, package, label, or hold a dietary supplement.

We did not receive comments specific to proposed § 111.30(b)(2). We have made nonsubstantive editorial changes to the rule. For example, proposed § 111.30(b)(2) would require you to ''make and keep'' written records; final § 111.35(b)(4) omits the words '' make and keep'' because that requirement appears earlier in § 111.35.

5. Final § 111.35(b)(5)

Final § 111.35(b)(5) (proposed § 111.30(b)(5)) requires you to make and keep backup file(s) of current software programs (and of outdated software that is necessary to retrieve records that you are required to keep in accordance with subpart P, when current software is not able to retrieve such records) and of data entered into computer systems that you use to manufacture, package, label, or hold dietary supplements. Under final § 111.35(b)(5)(i), your backup file (e.g., a hard copy of data you have entered, diskettes, tapes, microfilm, or compact disks) must be an exact and complete record of the data you entered. Under final § 111.35(b)(5)(ii), you must keep your backup software programs and data secure from alterations, inadvertent erasures, or loss.

(Comment 141) Several comments would limit the requirement for maintaining backup files of data entered into computer systems to those data entered into computer systems that are relied upon for compliance with CGMPs. These comments argue that the paragraph, as written, calls for a firm to make and keep backup files of data entered into computers on which personnel payroll records are maintained, and state that no such requirement should be imposed. Therefore, these comments would replace the words ''your computer system'' with the words ''any of your computer systems that are relied upon for compliance with this part.''

(Response) We have modified the provision to clarify that the requirement is for computer systems that you use to manufacture, package, label, or hold dietary supplements.

(Comment 142) Several comments argue that many software programs are in a near constant state of revision and that it is not a common business practice for a firm in any industry to maintain records of outdated software programs, at least if the firm is still able to use a revised program to access data it entered using an outdated program. The comments assert that, although the drug CGMPs require the maintenance of certain backup files of data entered into computer systems, they do not require the maintenance of backup files of software programs.

(Response) Keeping backup copies of software helps ensure that data can be retrieved if the primary software develops a problem. When we use the term ''backup,'' we mean a second copy of the software in question rather than a copy of previous versions of the software that are outdated, provided that data can be retrieved. However, if the data collected using outdated software cannot be retrieved by the newer software, there would still be a need to maintain a primary copy and a backup copy of the outdated software used to collect or manage the data.

We have narrowed the requirement to retain backup files of software to current software and of outdated software that is necessary to retrieve records that you are required to keep in accordance with subpart P, when current software is not able to retrieve such records.

(Comment 143) Some comments claim that, although the drug CGMPs require the maintenance of certain backup files of data entered into computer systems, they do not require the maintenance of backup files of software programs. Several comments also assert that it is not always possible to keep backup files of the software programs used in certain pieces of equipment, because the equipment manufacturer may be the only one having access to the programming of its equipment. The comments would delete the words ''software programs and'' from proposed § 111.30(b)(5).

(Response) In most cases, we anticipate that firms will have access to backup copies of their software programs. We acknowledge that in rare instances, backup copies may not be available and in these situations, we will take that into account in reviewing compliance with this provision. We decline to revise the provision as suggested.

6. Final § 111.35(b)(6)

Final § 111.35(b)(6) states that you must make and keep ''documentation of

the controls that you use to ensure that equipment functions in accordance with its intended use.''

The preamble to the 2003 CGMP Proposal stated that we were not proposing verification requirements for automatic, mechanical, or electronic equipment (68 FR 12157 at 12194). However, we invited comment on whether the final rule should require such verification (id.). Verification would ensure that the processes using automatic, mechanical, and electronic equipment consistently produce an outcome that meets a predetermined specification and any predetermined quality characteristics. Verification would show whether your automatic, mechanical, or electronic processes will consistently operate as they should.

(Comment 144) Several comments argue against including equipment verification requirements. The comments argue that the verification discussion in the preamble to the 2003 CGMP Proposal is difficult to distinguish from drug validation. The comments argue that validation should be allowed to evolve in the dietary supplement industry as it evolved in drug CGMPs. According to these comments, the dietary supplement industry, being largely self regulated in CGMPs to date and not generally practicing verification, would be more readily adaptable to, and better controlled by, strict operating controls and quality control checks including sufficient input and output checks on computer operated systems, than having to digest the concept of verification and implement verification processes. The comments state that, in the future, verification may be a means of offsetting some of the extensive testing of finished products.

Other comments state we should not require verification of processes that use automatic, mechanical, or electronic equipment given the different processes that dietary supplement manufacturers use. The comments argue that although dietary supplement manufacturers, depending on the unique circumstances of a particular manufacturing process, may choose to verify processes using a sound verification system, we should not require verification.

Several comments ask us to clarify whether we intended to require full validation of equipment used to process dietary supplements because terms such as ''suitability'' and ''capable,'' which we used in proposed § 111.30(a)(1) and (a)(2), might be interpreted to require validation. These comments state validation is unnecessary and overly burdensome for equipment used in manufacturing dietary supplements.

Several comments argue that proposed § 111.30(a)(1) and (a)(2) have the effect of establishing unnecessarily formal, stringent, and expensive validation requirements on equipment design, selection, and capability. The comment states that this language represents a de facto ''IQ/OQ/PQ'' (installation qualification/operational qualification/performance qualification) requirement. According to these comments, emphasis should instead be directed to actual use and operation.

In contrast, several comments argue we should require manufacturers to develop and maintain data that demonstrate that equipment is suitable and that the production process consistently delivers expected results. The comments argue that one key CGMP element is the requirement for systems to operate consistently and to produce an outcome that meets a predetermined specification. According to these comments, demonstration of system capability is best achieved through systems verification. The comments explain that, in an industry where the complexity of finished products often precludes finished product testing, the capability of the systems employed is of paramount importance. The comments state if the processes used fail to produce a product meeting predetermined specifications and quality characteristics, then the product should not be sold. The comments add that, although verification imposes additional costs on manufacturers, frequently rejected product, adequate rework procedures, and extensive in-process and finished product testing also would be costly.

Several comments also claim the use of an appropriate verification system may, under certain circumstances, allow for lot testing as opposed to batch testing. These comments state that, with process verification and an appropriate testing scheme, a manufacturer could demonstrate that lot testing provides sufficient assurance of quality and lack of adulteration. The comments ask us to address these alternatives in the final rule. Many comments said written records of verification should be maintained. The comments offer several suggestions on how this could be accomplished, including using statistical process control techniques or other appropriate statistical tools.

(Response) We used the term ''verification'' rather than ''validation'' to signal that we did not expect that a final rule would include requirements for formal process validation requirements, such as an IQ/OQ/PQ requirement, for equipment. Regardless, several comments interpreted our request for comments as a suggestion that we were considering such formal validation requirements. At this time, we are not requiring formal process validation for equipment. However, we will monitor the development of systems that evolve within this diverse industry.

We disagree that proposed § 111.30(a)(1) and (a)(2) would have the effect of establishing unnecessarily formal, stringent, and expensive validation requirements on equipment design, selection, and capability, and that the language would represent a de facto ''IQ/OQ/PQ'' requirement for equipment. Final § 111.30(e) requires you to ensure equipment operates in accordance with its intended use. We agree with the comments that argued that data demonstrating that equipment is suitable, and that the production process consistently delivers expected results, are a key element of CGMP. Therefore, final § 111.35(b)(6) requires you to make and keep documentation of the controls that you use to ensure that the equipment functions in accordance with its intended use. Examples of such controls include temperature settings, fill rates, and blending times that must be set, checked, and adjusted as necessary.

X. Comments on Requirement to Establish a Production and Process Control System (Final Subpart E)

A. Reorganization of Proposed § 111.35 Into Final Subpart E

In the 2003 CGMP Proposal, the requirements for a production and process control system were set forth in § 111.35. As shown in table 6 of this document, we are reorganizing proposed § 111.35 into subpart E. Table 6 lists the sections in final subpart E and identifies the sections in the 2003 CGMP Proposal that form the basis of the final rule.

TABLE 6.—DERIVATION OF SECTIONS IN FINAL SUBPART E

Final Rule	2003 CGMP Proposal
§ 111.55 What are the requirements to implement a production and process control system?	§ 111.35(a)
§ 111.60 What are the design requirements for the production and process control system?	§ 111.35(b)

TABLE 6.—DERIVATION OF SECTIONS IN FINAL SUBPART E—Continued

Final Rule	2003 CGMP Proposal
§ 111.65 What are the requirements for quality control operations?	§ 111.35(c)
§ 111.70 What specifications must you establish?	§ 111.35(e), (f), (g), and (k)
§ 111.73 What is your responsibility for determining whether established specifications are met?	§ 111.35 (f), (g), and (h)
§ 111.75 What must you do to determine whether specifications are met?	§ 111.35(e), (f), (g), (h), (i), (k), and (l) § 111.37 (b)(11)(iv) § 111.40(a)(2)
§ 111.77 What must you do if established specifications are not met?	§ 111.50(d)(2), (f), and (g) § 111.35(i)(4)(i) and (i)(4)(ii)
§111.80 What representative samples must you collect?	§ 111.37(b)(11)
§ 111.83 What are the requirements for reserve samples?	§ 111.37(b)(12) § 111.50(h) § 111.83(b)(2)
§ 111.87 Who conducts a material review and makes a disposition decision?	§ 111.35(i) and (n) § 111.37(b)(5) and (b)(14) § 111.40(a)(3) § 111.50(d)(1) § 111.85(a) and (c)
§ 111.90 What requirements apply to treatment, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification established in accordance with § 111.70 is not met?	§ 111.35(i)(4) § 111.50(d)(1), (f), and (g) § 111.65(d)
§ 111.95 under this subpart E, what records must you make and keep?	§ 111.35(m) and (o)

B. General Comments on Proposed § 111.35

(Comment 145) Several comments emphasize the first step in ensuring safe, high quality products is to use high quality components that meet well-defined specifications. Some of these comments assert the 2003 CGMP Proposal does not encourage development of such specifications.

Several comments assert that a more appropriate balance is needed between an effective process control system and a reasonable testing scheme that is calculated to confirm the quality of dietary supplements, and that it is important to provide companies with more flexibility in developing a specific CGMP program that satisfies the requirements. The comments stress it is important to build quality into a product throughout the entire production process by relying on strong process controls rather than by testing at the finished batch stage. One comment asserts that, in an appropriate process control system, testing is a means to monitor and ensure that the control system is functioning as intended. Many comments recommend the final rule include rigorous in-process controls plus a requirement for one identity test of incoming components to ensure quality and safety.

Many comments assert a certificate of analysis can be a key element of the manufacturing process provided that a manufacturer certifies that a vendor consistently supplies suitable product through a combination of vendor audits and product testing. (A certificate of analysis is a document, provided by the supplier of a component prior to or upon receipt of the component, that documents certain characteristics and attributes of the component.) Comments also assert that, with use of a certificate of analysis from a properly qualified supplier, the amount of required testing could be reduced. One comment notes that, although a certificate of analysis may not be relied upon completely to forgo testing of a received ingredient, the extent of testing could be reduced to take into account the history of the supplier in providing quality ingredients. This and other comments recommend the dietary supplement manufacturer conduct identity tests to ensure that the correct component has been received. A few comments note that the drug CGMP regulations permit the use of a supplier's certificate of analysis based upon certification of the supplier by a program of complete testing for conformance with the certificate of analysis.

Several comments support the use of a qualified supplier's certificate of analysis in lieu of testing at the finished batch stage. One comment recommends testing be strategically employed to verify that other control procedures have accomplished their intended result; if other controls are adequate, a statistically-based testing program should be permitted for finished batches rather than the proposed requirement for testing every batch for every specification.

Many comments note that section 402(g)(2) of the act directs us to develop dietary supplement CGMP requirements that are modeled after the CGMP regulations for food. These comments point out that, because the food CGMPs allow the use of a verified certificate of analysis, it is unfair and illogical to disallow a certificate of analysis in the dietary supplement CGMP final rule. One comment states the proposed requirements for production and process controls are more stringent than the requirements for drug products.

Several comments stress that the most critical aspect of a successful CGMP system is effective process control, which includes a requirement for written procedures and documentation for all key processing operations. Many comments argue that effective process control, including extensive written procedures, should allow for a decreased testing burden with respect to the finished product. One comment suggests we exempt manufacturers from the requirement to test each batch of finished product if they have a qualified manufacturing process that meets certain basic criteria, including a requirement for written procedures for each stage of the process and a written plan for qualifying this process.

Several comments urge us to build more flexibility into the testing requirements, in both the type and number of tests required and the point(s) in the supply chain at which they would be required. Some comments recommend that the frequency of testing be established under a statistically valid method to ensure that in-process controls are adequate to guarantee production of a safe and effective dietary supplement or ingredient. Several comments recommend we require manufacturers to test incoming ingredients and raw materials, in lieu of testing each finished batch of product. These comments state it is more prudent to test to ensure that the materials used in formulating a product are appropriate and safe than to risk making an adulterated product and, in so doing, contaminate manufacturing equipment.

Several comments recommend we allow manufacturers to employ skip-lot testing as an alternative to testing each finished batch of product. One comment states that, with adequate process controls in place, periodic or skip-lot testing is sufficient, and notes that skip-lot testing is acceptable under the regulatory frameworks for herbal

products in other countries, including Canada and countries in the European Union.

In summary, the comments suggest an approach that stresses the importance of establishing specifications for components, relying on a certificate of analysis from a qualified supplier for certain specifications with qualification of the suppliers, and establishing and following written procedures. This overall approach would focus on building quality into a dietary supplement throughout the production and process control system. The role of testing at the finished batch stage would become a check on whether the overall manufacturing process is, in fact, under control.

(Response) Based upon a review of the comments, we have reconsidered the approach taken in the 2003 CGMP Proposal. The 2003 CGMP Proposal would require that all finished batches of dietary supplements be tested at the finished batch stage to ensure that the products met specifications for identity, purity, strength, and composition. The 2003 CGMP proposal recommended, but would not require, testing of incoming components to ensure that component specifications, including identity, were met. However, if a specification (such as identity) could not be tested at the finished batch stage, the proposed rule would require a firm to test incoming components for that specification and to test for that specification at the in-process stage as necessary to ensure that products met specifications. We are persuaded that, as an alternative to testing each finished batch of product, we can allow for the use of a statistically sound sampling and testing program for finished batches of dietary supplements unless a manufacturer chooses to test every batch. Such a sampling and testing program is feasible when controls are implemented earlier than the final product stage in the manufacturing process. Controls include the use of a certificate of analysis from a qualified supplier for specifications other than the identity of a dietary ingredient, and the establishment and monitoring of in-process manufacturing controls. We agree with the comments that if we reduce the requirements for testing at the finished batch stage, then it is critical that you determine whether components meet specifications. We address this issue in the following two ways: (1) Each manufacturer must confirm the identity of each component prior to use (you must test or examine dietary ingredients to verify the identity, but may rely on a certificate of analysis to confirm the identify of components other than dietary ingredients) and (2) each company must confirm other required specifications for components prior to use, either by relying upon a certificate of analysis or by testing or examining the component.

As the comments have suggested, specifications for the ''identity'' of components of dietary supplements are critically important. These comments included references to industry proposals that supported identity testing. The 1997 ANPRM (62 FR 5700) included an industry proposed outline of CGMP provisions which contained a provision that required identity testing as follows: ''(iv) Each lot of raw material shall undergo at least one test by the manufacturer to verify its identity. Such tests may include any appropriate test with sufficient specificity to determine identity, including chemical and laboratory tests, gross organoleptic analysis, microscopic identification, or analysis of constituent markers.'' (60 FR 5700 at 5705).

In January 2004, a group of trade associations representing dietary supplement manufacturers and others submitted text of proposed CGMP requirements to the docket as an alternative to the 2003 CGMP Proposal. This submission also included a provision which required identity testing as follows:

(1) For components, dietary ingredients, or dietary supplements that you receive, you must:

(i) conduct at least one test or examination to verify that the specifications for identity are met; * * *

(1996N–0417, EMC000261–02 at 20).

Both the 1997 ANPRM industry outline and the January 2004 industry docket submission included provisions that allowed certificates of analysis to establish specifications other than for identity for ingredients and components.

In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12162) we discussed a case in which *Digitalis lanata* was labeled as plantain and, as a result, a young woman experienced a life-threatening abnormal heart function after consuming a dietary supplement containing *D. lanata* in lieu of plantain. The problem occurred notwithstanding the fact that certificates of analysis furnished by the supplier provided assurances that the component was indeed plantain.

Because of the critical importance of ensuring the proper identity of dietary ingredients—they are the central defining ingredients of a dietary supplement—we are requiring each firm that uses a dietary ingredient to perform its own testing or examination for identity of each dietary ingredient prior to use. This requirement is similar to the proposed requirement set forth by industry in both the 1997 ANPRM and in the January 2004 industry comment to the proposed rule. Firms may not rely upon a certificate of analysis provided by suppliers to determine the identity of a dietary ingredient before use. We recognize, however, that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would provide no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we decided to provide, in an interim final rule published elsewhere in this issue of the **Federal Register**, a procedure that allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met.

In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12198), we explained that we would not permit firms to rely upon supplier certifications. The decision was based, in large part, on problems that have occurred with faulty certificates in the past. We have, however, reconsidered our position on certificates for specifications, other than for the identity of the dietary ingredients, based on comments discussing how firms have taken steps to ensure that their certificates are reliable. We believe that the minimum criteria that we are establishing for a certificate of analysis, together with the requirement that a firm relying on a certificate of analysis must qualify a supplier and periodically repeat that qualification process, can prevent the problems that have occurred with faulty certificates in the past. Therefore, for component specifications, other than the identity of a dietary ingredient, including confirming the identity of components that are not dietary ingredients, we are permitting firms to rely upon certificates of analysis provided by suppliers, if the certificates meet the requirements of the final rule. Under final § 111.75(a), a firm may rely upon a certificate of analysis from its supplier of a component, provided that certain criteria are met which include the following: (1) The

firm first qualifies the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations; (2) the certificate of analysis includes a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations; (3) the firm maintains documentation of how it qualified the supplier; (4) the firm periodically reconfirms the supplier's certificate of analysis; and (5) the firm's quality control personnel review and approve the documentation setting forth the basis for qualification (and requalification) of any supplier.

As we discussed in the preamble to the 2003 CGMP Proposal, in-process controls are necessary to ensure that dietary supplements are manufactured in accordance with their specifications (68 FR 12157 at 12197). Under final § 111.75(b), firms must monitor the in-process points, steps, or stages where control is necessary to ensure the quality of the finished batch of the dietary supplement to: (1) Determine whether the in-process specifications are met and (2) detect any deviation or unanticipated occurrence that may result in a failure to meet specifications. In addition, we have strengthened the requirements for in-process controls by requiring that quality control personnel conduct all required material reviews and make all required disposition decisions using written procedures to ensure that deviations or unanticipated occurrences that occur are consistently handled.

Because of the strengthened requirements regarding component and in-process specifications, the final rule permits testing of a subset of finished batches rather than requiring testing of each finished batch. Consistent with several suggestions in the comments, we built more flexibility into the testing requirements so that a firm may test a subset of finished dietary supplement batches that the firm identifies through a sound statistical sampling plan for selected specifications rather than test every batch of the finished dietary supplement for every specification. Finally, quality control personnel must review and approve any exceptions from testing requirements that are allowed under the rule and the basis for such exceptions. This approach is consistent with the comments that we received and will achieve a high degree of integrity in the manufacturing process, while at the same time provide flexibility to the industry.

Additional discussion on the requirements for identity testing of dietary ingredients and the appropriate reliance on a certificate of analysis for components other than dietary ingredients is found in this section in response to comment 174.

C. Final Subpart E and Highlights of Changes to the Proposed Regulations

The provisions in final subpart E reflect that the final rule applies only to persons who manufacture, package, label, or hold a dietary supplement unless subject to an exclusion in final § 111.1. The approach that we are incorporating into the final rule requires changes in most of the individual paragraphs of proposed § 111.35.

D. What Are the Requirements to Implement a Production and Process Control System? (Final § 111.55)

Final § 111.55 requires you to implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.55 derives from proposed § 111.35(a).

(Comment 146) A few comments say the production and process controls outlined in proposed § 111.35 are critical in ensuring that dietary supplements meet specifications for identity, purity, quality, strength, and composition. One comment recommends proposed § 111.35(a) be revised to state ''* * * that covers all stages of manufacturing, packaging, labeling, and holding of * * * dietary supplements that occur in your facility or for which you otherwise have responsibility.'' This comment explains that the production of dietary supplements is often broken up into several stages which are under the control of different entities. The comment gives the following examples: A marketing company may manufacture and package a product itself; or it may contract with one company to manufacture and package the product; or it may contract with one company to manufacture the product and another company to package the product; and contract manufacturers and packagers may subcontract portions of the manufacturing or packaging.

(Response) We decline to revise the rule as suggested by the comments. As we discussed in response to comment 37 in section VI of this document, you must comply with the CGMP requirements that apply to your operations related to the manufacturing, packaging, labeling, and holding of dietary supplements. We decline to include codified language that may not capture all of the possible relationships that exist in a given operation.

E. What Are the Design Requirements for the Production and Process Control System? (Final § 111.60)

Final § 111.60(a) requires that your production and in-process control system be designed to ensure that the dietary supplement is manufactured, packaged, labeled, and held in a manner that will ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.60(b) requires that the production and in-process control system include all requirements of subparts E through L of part 111 and be reviewed and approved by quality control personnel. Final § 111.60(a) and (b) derive from proposed § 111.35(b).

As discussed in section III of this document, we are clarifying a number of provisions that did not explicitly identify labeling as an operation that is covered by the rule. Final § 111.60 is one such provision. Under proposed § 111.35(a) we would require that you implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary supplements. In an oversight, proposed § 111.35(b) would require your production and in-process control system to be designed to ensure that the dietary supplement is manufactured, packaged, and held—but not labeled—in a manner that would prevent adulteration of the dietary supplement. To correct this oversight, final § 111.60 explicitly identifies labeling as an operation that the design of your production and process control system must address.

(Comment 147) A few comments recommend that the phrase ''designed to ensure'' in proposed § 111.35(b) be deleted because it requires that formal, prospective studies (similar to a process validation) must be performed and such a requirement would be unduly burdensome.

(Response) We disagree with the comments' interpretation of the proposed regulation and decline the request. Final § 111.60(a) relates to the overall design of your production and process control system. It does not require validation based on scientific studies, but rather that your process contain all the controls necessary to ensure the quality of your dietary supplements and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. The process, for example, must

ensure that the dietary supplement meets all specifications established under § 111.70(e).

F. What Are the Requirements for Quality Control Operations? (Final § 111.65)

Final § 111.65 requires that you implement quality control operations in your manufacturing, packaging, labeling, and holding operations for producing the dietary supplement to ensure that these operations are performed in a manner that ensures the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.65 derives from proposed § 111.35(c).

Proposed § 111.35(c) referred to the role of the quality control unit in manufacturing, packaging, and label operations—but not in holding operations. This was an oversight. We, therefore, revised proposed § 111.35(c) to include ''holding'' as an operation that is subject to the oversight of quality control personnel for consistency with final § 111.105 (proposed § 111.37(a)), which provides for the performance of quality control operations to ''ensure that your manufacturing, packaging, label, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.''

(Comment 148) One comment recommends proposed § 111.35(c) be revised to state ''ensures that the * * * dietary supplement meets manufacturing specifications for identity, purity, quality, strength, and composition.''

(Response) We are not making this change because it is unnecessary in the context of the provisions of final § 111.65.

(Comment 149) One comment argues that proposed § 111.35(c) is too wordy and needs clarification. The comment recommends it be revised to state ''You must use a quality control unit to ensure that the dietary supplement meets specifications for identity, purity, quality, strength, and composition.''

(Response) We disagree with this comment. The change requested by the comment would emphasize a single responsibility of quality control personnel (i.e., releasing final product) and would obscure the fact that quality control personnel have a role in the design and conduct of most of your operations.

(Comment 150) One comment recommends proposed § 111.35(c) be revised to state ''ensures that the * * * dietary supplement meets specifications for identity, purity, quality, strength, and composition as appropriate to protect the public health; and quality, strength, and composition as appropriate for the * * * product.'' This comment states it is confusing and unnecessary to require that all five of these attributes be addressed for all dietary supplements. The comment also states the term ''purity'' requires explanation because not all ingredients or supplements are subject to the same types of contamination.

(Response) We are not making any changes in the provision as suggested by this comment. The comment provides no basis for the assertion that the proposed requirement to use a quality control unit to ensure that a dietary supplement meets specifications for identity, purity, strength, and composition is confusing and unnecessary. In section VI of this document, we explain that purity means that portion or percentage of a dietary supplement that represents the intended product.

G. What Specifications Must You Establish? (Final § 111.70)

Final § 111.70 derives from proposed §§ 111.35(e), (f), (g), and (k), 111.37(b)(11)(iv), and 111.70(c).

(Comment 151) Some comments state proposed § 111.35(k), which would require that you test or examine components and dietary supplements for those types of contamination that may adulterate or lead to adulteration, is more appropriate for, and should be incorporated into, proposed § 111.35(e) which would require, in part, that you establish specifications for the identity, purity, quality, strength, and composition of components that you receive and of dietary supplements that you manufacture. The comments note this suggestion would help simplify and eliminate some redundancy in proposed § 111.35. One comment would revise proposed § 111.35(k) to state ''Purity specifications for purchased or manufactured components and dietary supplements must be established for those types of contamination which can reasonably be expected to affect the component, ingredient, or supplement in question * * *.'' According to the comment not all ingredients or supplements are subject to the same types of contamination, and it would be unduly burdensome to require that all ingredients and supplements be tested for all possible contaminants (as opposed to all likely contaminants).

(Response) We agree that not all ingredients or dietary supplements are subject to the same types of contamination. It would not be practicable or necessary to require testing for all possible contaminants for every dietary supplement, or for every component used to manufacture a dietary supplement. As we explained in the 2003 CGMP Proposal (68 FR 12157 at 12199 through 12200), the manufacturer has the responsibility to determine what types of contamination are likely or certain to contaminate a given product and to determine what types of tests to conduct and when to test for such contamination. We explained that botanicals are likely or certain to contain filth and microorganisms of public health significance based on the areas in which they are harvested (id.). As another example, fungal growth on a botanical component can provide the environment for mycotoxin production, especially aflatoxin (id.). If fungal growth is present, the manufacturer would need to perform an appropriate test that can detect the toxic substance. We stated that the manufacturer must be aware of potential contamination, regardless of whether due to filth, insects, microorganisms, or toxins and to test or examine, as appropriate, the components and dietary supplements for those types of contamination that may adulterate or that may lead to adulteration (id.). Thus, the types of contamination that we were referring to in proposed § 111.35(k) are those that are likely or certain to be present in or on components received, based on the nature of the product, its source, handling prior to receipt by the facility, or other reason, and not due to poor manufacturing practices that resulted in their presence in the first instance.

It is the responsibility of the manufacturer to identify those contaminants and to establish limits to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act. For example, if you manufacture a polysaccharide that derives from seaweed, it is likely that you would include a limit on cadmium, because cadmium is a common contaminant that can be present in marine-derived ingredients. If you manufacture a polysaccharide that has a composition similar to seaweed-derived polysaccharide, but derives from a land-based plant, it is not likely that you would include a limit on cadmium, because cadmium is not a common contaminant of land-based plants. Likewise, if you manufacture a mineral that contains phosphates, it is likely that you would include a limit on arsenic, because phosphates are generally mined and arsenic is a common contaminant that can be present in ingredients that

are mined. If you manufacture a mineral that does not include ingredients that are mined, it is not likely that you would include a limit on arsenic.

We agree that controlling contamination is critical to the quality of the dietary supplement. However, we do not agree that the types of contamination addressed by proposed § 111.35(k) should be considered as a purity specification. We have described purity in this final rule to mean something that you intend to be present in the final product. As explained in section VI of this document, purity means that portion or percentage of a dietary supplement that represents the intended product. For example, you may manufacture a dietary supplement that uses a natural product such as fish oil to provide triglycerides that are a source of the polyunsaturated fatty acids DHA and EPA. The purity refers to the percent of the fish oil that is triglycerides. (Note that if you are manufacturing fish oil to provide the fatty acids DHA and EPA in the dietary supplement, the component specifications for the fish oil must include a strength specification for DHA and EPA in whatever amount you determine is necessary to meet the specification for strength of DHA and EPA in the dietary supplement.) If the natural product also contains lead, or other unwanted ingredients that may adulterate or may lead to adulteration, you would have to establish limits for such contaminants. Thus, to distinguish the proposed requirement in § 111.35(k), which relates to contaminants that may be present on or in the components that you receive, from the requirements related to specifications for desired characteristics of identity, purity, strength, and composition, we are including a separate requirement on establishing limits on such contaminants for components that you receive (final § 111.70(b)). We also include a requirement for establishing an in-process specification for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met, as necessary, for limits on contamination. In addition, we are including a requirement for such limits on contaminants in the finished batch of dietary supplement (or subset of finished batches) (final § 111.70(e)) to ensure that the manufacturing process has not adversely affected such levels, e.g., has not contributed an additional source of such contaminant or failed to remove the contaminant, when necessary. Such limits would need to ensure the quality of the dietary supplement, i.e., to ensure that the dietary supplement has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

Thus, in addition to the presence of contaminants that may be in or on components that you receive, there may be sources of contamination that you need to control for in your facility. As discussed in this section, you must establish specifications under final § 111.70(a) and (c) to prevent adulteration from such sources. The specifications established under final § 111.70(a) and (c) may or may not include limits on such contaminants. By ''limits on those types of contamination'' in final § 111.70, we do not mean contamination from, for example, the presence of rodent pellets or other filth that would constitute an insanitary condition under section 402(a)(3) or (a)(4) of the act, if such filth was present in your facility. You are not allowed to establish specifications for limits on contaminants that would otherwise adulterate your product under the act if such contaminants were present.

Further, in proposed § 111.35(k), we included a listing of the types of contamination we considered to be applicable to dietary supplements (68 12157 FR at 12258). We stated that the types of contamination include: (1) Filth, insects, or other extraneous material; (2) microorganisms; and (3) toxic substances. We have deleted the listing of the types of contamination in the final rule because the listing is simply informative and establishes no independent requirement. We received several comments, discussed in the following paragraphs, on the types of contamination that may be present, some which were solicited by us in the 2003 CGMP Proposal (68 FR 12157 at 12179 through 12181).

In the 2003 CGMP Proposal, we solicited comment on whether we should include in the final rule specific requirements for manufacturing, packaging, or holding animal-derived dietary ingredients, because animal-derived dietary ingredients present important public health and safety issues.

In the 2003 CGMP Proposal, the example we used was an animal-derived dietary ingredient potentially contaminated with the agent that causes bovine spongiform encephalopathy (BSE), which is a type of transmissible spongiform encephalopathy (TSE). TSEs are fatal, neurodegenerative disorders, which have been identified in humans and a number of animal species (e.g., cattle, sheep, goats, elk, deer, cats, and mink), but primarily in ruminants (cattle, sheep, elk, deer) (69 FR 42256, July 14, 2004). Most scientists believe that variant Creutzfeldt Jakob Disease (vCJD), a progressive neurological disease in humans, is caused by consumption of cattle products contaminated with the agent that causes BSE (69 FR 42256 at 42257).

In the 2003 CGMP Proposal (68 FR 12157 at 12180), we stated that we had communicated with the public and manufacturers of FDA-regulated products about appropriate steps to increase product safety and minimize the risk of products contaminated with the BSE agent. We referenced a notice in the **Federal Register** of August 29, 1994 (59 FR 44591), entitled ''Bovine-Derived Materials; Agency Letters to Manufacturers of FDA-Regulated Products.'' We sent letters to dietary supplements manufacturers to alert them to the developing concern about TSEs in animals and Creutzfeldt-Jakob Disease in humans. We recommended they investigate the source of any bovine and ovine material used in their products. We suggested that manufacturers develop plans to ensure, with a high degree of certainty, that bovine and ovine materials used in their products were not from BSE countries or from sheep flocks (foreign or domestic) infected with scrapie. We stated that our Center for Biologics Evaluation and Research (CBER) had developed guidances for industry that describe steps manufacturers should take to ensure the safety and suitability for human use of animal-derived biologics. We also stated that we were considering whether the procedures that CBER recommends for a product with animal-derived materials, substances, or tissues would be appropriate for dietary ingredients and dietary supplements that contain animal-derived materials, substances, or tissues. We believed that the use of an animal-derived material, substance, or tissue in a dietary supplement may raise many of the same serious public health and safety issues as animal-derived materials, substances, or tissues, in a biologic. We invited comment on whether there is a scientific basis for us to treat animal-derived dietary ingredients in a manner different from, or that would offer less protection than, what is recommended for animal-derived biologics when the same public health and safety risks may be present.

(Comment 152) Several comments state there should not be specific requirements for manufacturing, packaging, or holding animal-derived dietary ingredients because BSE issues

are not specific to dietary supplements, and because other guidance and regulations, issued by FDA and by the U.S. Department of Agriculture (USDA), already address BSE and public health. Other comments state it would be appropriate to include specific CGMP requirements for BSE as long as the requirements reflect the thinking in currently existing regulations and guidance.

Several comments do not support the need for additional provisions regarding the handling of imported animal-derived ingredients because the industry has already taken steps to comply with the requirements or recommendations issued by either USDA or FDA. The comments state that the regulations issued by USDA for meat related products in the food industry provide adequate control over the use of animal tissues that might contain microorganisms, specifically viruses, of public health concern.

One comment argues that if purchases of domestic raw tissues have been inspected by USDA, it is unfair to impose additional regulations simply because these tissues are included in dietary supplements. This comment asserts it would be unfair to require testing of animal-derived products given the fact that there are no tests for BSE available, and that reliance on USDA and FDA is the best way to stop the spread of BSE.

Another comment states that industry trade associations have been working actively with their member companies to ensure adherence to the requirements set forth in our various letters regarding the need to develop plans ''that ensure, with a high degree of certainty'' that animal-derived ingredients are used only in accordance with FDA and USDA policies designed to protect against BSE. The comment states that a summary of industry procurement and handling practices regarding animal-derived ingredients (submitted to us) contains lists of animal-derived ingredients used by various companies, with examples of the certificates of origin and other documentation required for import of any animal-derived materials. One comment states that industry members who handle animal-derived ingredients already have implemented many of the controls that originated either from USDA or the dietary ingredient suppliers in response to demands by various governments or consumers, and that such matters should remain with USDA to avoid duplication of effort.

Some comments oppose any recommendation that guidance issued by CBER for ensuring the safety and suitability for human use of animal-derived biologics apply to dietary supplement products. One comment includes a review of literature on BSE and claims the review justifies not applying the CBER guidances on BSE to dietary supplement products under part 111.

(Response) For cattle derived materials, you must comply with the requirements of the interim final rule on BSE set forth in § 189.5 (see 70 FR 53063, September 7, 2005) and any subsequent modifications. Under the interim final rule, no human food, including dietary supplements, shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials as defined in the rule. In addition, manufacturers and processors of such food that is manufactured from, processed with, or otherwise contains, cattle material must make existing records relevant to compliance available to us for inspection and copying. For both cattle-derived and other animal-derived materials, you must comply with all applicable provisions of this final rule. For example, under final § 111.70, you must establish specifications for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. Thus, you must establish specifications for your animal-derived materials that are necessary to ensure the quality of the dietary supplement. Ensuring quality includes preventing contamination that may adulterate the product under section 402(a)(1), (a)(2), (a)(3), or (a)(4) of the act. In addition, you must take actions to determine whether the specifications are met (final § 111.73). Therefore, if you used animal-derived materials other than prohibited cattle materials subject to the BSE interim final rule, you would need to establish specifications necessary to ensure the quality of the dietary supplement.

The guidances issued by CBER are still in effect for animal-derived biologics, and we continue to recommend that you use them as appropriate for your products that contain animal-derived ingredients.

(Comment 153) One comment agrees with the provisions of proposed § 111.35(k) but requests that we provide guidance to the industry on allowable limits for the types of contamination listed. Another comment asks us to develop specific defect action levels (DALs) for dietary supplements as more information becomes available, rather than rely on existing DALs from the food industry.

(Response) In the 2003 CGMP Proposal (68 FR 12157 at 12163), we stated that we were not identifying DALs for the types of contaminants for dietary ingredients because there are not enough data available to identify an appropriate DAL for most dietary ingredients. These comments do not provide data, or evidence that data are available, to enable us to issue guidance for DALs for specific contamination. Therefore, we are not taking the action requested by these comments. We discuss DALs in this section in response to comment 156.

(Comment 154) Some comments suggest the provisions in proposed § 111.35(k), testing for contamination that could adulterate a product, would be more appropriate to include in proposed § 111.35(e), which concerns the establishment of specifications.

(Response) We agree with these comments and are including requirements to include limits on contamination in final § 111.70. The requirements set forth in final §§ 111.70 and 111.75 are consistent with this comment. Under final § 111.70(b) you must establish limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement. Under final § 111.70(c) you must establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplements, and as necessary, limits on contamination for those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement. Under final § 111.70(e), you must establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement. As we explained in the response to comment 151, by ''limits on those types of contamination'' in final § 111.70, we do not mean contamination from, for example, the presence of rodent pellets or other filth that would constitute an insanitary condition under section 402(a)(3) or (a)(4) of the act, if such filth was present in your facility. You are not allowed to establish specifications for limits on contaminants that would otherwise adulterate your product under the act if such contaminants were present.

(Comment 155) Several comments object to proposed § 111.35(k) because

the provision would be more stringent than the food or drug CGMP requirements. Some point out that the consumption levels for food are higher than for dietary supplements. A few comments argue that proposed § 111.35(k) is too broad as it requires testing or examination for those contaminants that ''may'' adulterate or ''may lead to'' adulteration, which could be interpreted to mean testing for unknown contaminants of every description. The comments suggest that this provision be revised to require testing or examination for those types of contamination that ''may be present in an amount or at a level'' that may adulterate or lead to adulteration or that ''may reasonably be expected'' to adulterate or lead to adulteration. Other comments agree that to test for all possible contaminants would be burdensome.

Several comments state that manufacturers should be allowed to rely on a supplier's certificate of analysis and that testing should not be required for every potential contaminant. One comment recommends that CGMPs should be specific to the source and that testing should depend on the nature of the material.

Some comments note that for botanicals it is sometimes nearly impossible to identify and analyze all naturally occurring substances.

(Response) The final rule does not include any specific requirements to test or examine components or dietary supplements for contamination. Rather, under final § 111.70(b), (c), and (e), you are required to establish specifications for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement. Under final § 111.73, you must determine whether the specifications established under § 111.70 are met. Final § 111.75(a) through (d) sets forth the criteria you must use to determine whether the specifications that you establish under final § 111.70(b), (c), and (e) are met. Consistent with these comments, under final § 111.75(a) you may rely on a certificate of analysis (other than for the identity of a dietary ingredient) from a qualified supplier of components to ensure that specifications that include limits on contamination are met, provided you satisfy the criteria set forth in final § 111.75(a). This would include, for example, relying on a certificate of analysis to ensure that the level of lead in each of your components would not adulterate the dietary supplement.

In determining compliance with the requirements to set limits for those types of contamination that may adulterate the dietary supplement or lead to adulteration for received components, we would not expect you to set limits for every potential contaminant or for every naturally occurring constituent of a botanical. Rather, we agree with the comments that the substances you would consider when determining whether to set limits for particular types of contamination would vary depending on the source of a component, such as a plant source, an animal source, a microbial source, or a marine source.

(Comment 156) Some comments point out that some compounds, such as mycotoxins, that are toxic at higher levels are detectable in nearly all plant ingredients and are found in the food supply. A few comments assert that dietary ingredients should not contain levels of certain toxic compounds that are higher than reasonable or higher than recognized maximum allowable limits as opposed to the zero tolerance for toxic compounds contained in the 2003 CGMP Proposal.

One comment requests clarification of the term ''toxic substances.'' One comment points out that information for identifying potential adulterants is provided in monographs. Another comment requests clarification on whether dietary supplement manufacturers will be required to test for toxins while food manufacturers, who may use some of the same ingredients, will not.

(Response) As the comments point out, the food supply does contain some degree of contaminants such as mycotoxins that can be found, for example, in certain grain. We do not have a ''zero tolerance'' policy for such unavoidable contaminants but we have issued some regulations and guidance to address certain common contaminants. We also have issued a booklet entitled ''Action Levels For Poisonous Or Deleterious Substances In Human Food And Animal Feed'' (Ref. 30; available at *http://www.cfsan.fda.gov*). The booklet is a useful resource for manufacturers who seek information about common contaminants that may adulterate a dietary supplement product or lead to adulteration. Another resource is the Foods Chemical Codex,[9] which includes monographs on many substances, such as salts that are used as sources of minerals used in both dietary supplements and conventional food. These monographs include limits on common contaminants, such as lead or other heavy metals. In addition, the regulations in 21 CFR part 109 provide information about certain contaminants.

(Comment 157) One comment recommends that all finished products be tested for microorganisms. Another comment contends the manufacturer should be allowed to restrict testing to the raw material if the facility and equipment are monitored for contamination. Some comments point out that contaminants may be detectable in raw materials but not in the finished product.

(Response) We disagree that all finished products must, as a matter of course, be tested for contamination with microorganisms. Whether it is necessary to test the finished product for microorganisms would depend, for example, on the characteristics of your product, the nature and source of your components, the specifications you establish for microbial contaminants in your components and whether these specifications are addressed in a certificate of analysis, the in-process specifications you establish, and the nature of your manufacturing process. However, these comments raise an important point—i.e., that microbial contamination could occur at your facility even if an incoming component is free of microorganisms. Final subpart K discussed in section XVI of this document, sets forth requirements for your manufacturing operations. Many of these requirements are designed to limit the potential for contamination with microorganisms.

(Comment 158) Some comments would revise the requirements for establishment of specifications for in-process controls (proposed § 111.35(e)(2)) and the finished batch of dietary supplements (proposed § 111.35(e)(3)), so that specifications for attributes of quality, strength, and composition are not required for a product that does not purport to possess such attributes.

(Response) We decline to reword the provision as requested by these comments. The requirement to establish specifications for strength and composition relate to the manufacturers' responsibility to know what their finished dietary supplement is

[9]The Food Chemicals Codex (FCC) project is an activity of the Food and Nutrition Board of the Institute of Medicine. The FCC was intended to provide standards for the purity of food chemicals and thus promote uniform quality and ensure safety in the use of such chemicals. The First Edition of the resulting FCC, published in 1966, was limited to chemicals added directly to foods to achieve a desired technological function. Succeeding editions upgraded the specifications for these substances and added specifications for substances that come into contact with foods and some that are regarded as foods, rather than as additives. The FCC is available for purchase at 1–800–624–6242 or at *http://www.nap.edu*.

composed of so that their products are consistently manufactured. Establishing specifications and following these CGMP requirements will help ensure the quality of the dietary supplement. The requirement to establish specifications is not limited to when a manufacturer purports that its product possesses attributes of strength and composition on the label. As discussed in the 2003 CGMP Proposal (68 FR 12157 at 12162), the absence of minimum standards has contributed to the adulteration and misbranding of dietary supplements because of contaminants or because manufacturers do not set and meet specifications for their products, including specifications for identity, purity, strength, and composition and do not set and meet limits on contaminants, when necessary. The comment does not persuade us otherwise. We note, however, that the final rule's requirements to establish specifications for components do, in fact, provide flexibility so that you are not required to establish a component specification for certain attributes, such as the strength of a tablet coating agent (see the discussion of final § 111.70(b) in this section).

(Comment 159) One comment asks for guidance as to what constitutes an official or scientifically valid standard for specifications.

(Response) We are not aware of any officially recognized standard for specifications. Specifications are critical standards that are proposed and justified by the manufacturer for each product that the manufacturer produces. The manufacturer establishes the set of criteria to which a product should conform to be considered acceptable for its intended use. In general, a specification may include a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described.

(Comment 160) One comment asks that we clarify whether every specification sheet must include separate, specific qualitative or quantitative standards, and tests to be established for each attribute, or whether a specification sheet can be modeled after a compendial monograph. Some comments state that product specification sheets should be modeled after pharmacopoeia monographs other than those listed in the preamble to the 2003 CGMP Proposal.

(Response) These CGMP requirements do not establish any requirements to have a ''specification sheet.'' Rather, the final rule (final § 111.70(a)) requires you to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. We require that you establish specifications for components (final § 111.70(b)), in-process production (final § 111.70(c)), labels and packaging (final § 111.70(d)), the finished batch of dietary supplement (final § 111.70(e)), product that you receive from a supplier for packaging and labeling (final § 111.70(f)), and the packaging and labeling for the finished packaged and labeled dietary supplement (final § 111.70(g)). The general requirement for establishing specifications in final § 111.70(a) includes specifications, not otherwise required in final § 111.70(b) through (g), that the manufacturer determines are necessary to achieve quality, i.e., that are necessary to meet the identity, purity, strength, or composition of the dietary supplement or that are necessary to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

Requirements to establish specifications to control for contamination are included in final § 111.70(a), (b), (c), and (e). As discussed earlier, the specifications for contaminants in final § 111.70(b) refer to those types of contamination of a component or dietary supplement that may adulterate or that may lead to adulteration that are due to contaminants that may be present in or on the components that you receive, based on the nature of the product, its source, its handling prior to receipt, or other reason. Limits are established by the manufacturer for such contaminants at receipt.

The requirement to establish specifications to control for contamination under final § 111.70(a) and (c) include specifications necessary to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act as a result of what the manufacturer may do or fail to do in its manufacturing operation, and not as a result of contaminants that are in or on the components received. For example, it may be critical that a certain piece of equipment be cleaned and/or sanitized after handling certain raw materials to ensure that there is no microbial contamination from microorganisms of public health significance to components processed on the equipment. If the manufacturer failed to establish a specification for cleaning and/or sanitizing after handling those raw materials before processing components, the manufacturer would have failed to establish a specification required by final § 111.70(a) or (c) necessary to prevent a type of contamination that may lead to adulteration under section 402(a)(4) of the act. We would consider it a failure to follow CGMP requirements if a manufacturer allowed conditions in the manufacture of a dietary supplement that would not ensure the quality of the dietary supplement.

We have specified in final § 111.70(b) that you must establish certain types of specifications that are critical to ensuring that you know what the components are that you use in manufacturing a dietary supplement and that are necessary to ensure that the dietary supplements you manufacture meet their specifications for identity, purity, strength, composition, and do not exceed their limits for contaminants. The identity, purity, strength, and composition, and the limits that you establish for contaminants, for a finished batch of dietary supplement are what we call ''product specifications'' in final § 111.70(e). These product specifications must be met in order for you to ensure the quality of your finished batch of dietary supplement. A specification may include a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described. For example, a specification for a component may include information about the test used to verify the identity of the component and the range of test results that are acceptable. Under final § 111.70(c), a specification for an in-process control may include information about the viscosity that must be achieved during a batch production of a liquid product and information about the test or equipment used to measure the viscosity. Under final § 111.70(d), a specification for packaging may include the specific type or grade of plastic. Under final § 111.70(e), a specification for the finished batch may include the quantitative amount of a dietary ingredient, such as vitamin C.

Under this final rule, the manufacturer has the flexibility—and the responsibility—to develop specifications that are appropriate to the circumstances, including whether information in any particular monograph is an appropriate model for a given dietary supplement.

1. Final § 111.70(a)

Final § 111.70(a) requires you to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to

ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.70(a) derives from the opening statement in proposed § 111.35(e).

As we discussed in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12196), the points, steps, or stages where specifications must be established may include heating steps, cooling steps, points where specific sanitation procedures are needed, product formulation control steps, points where cross-contamination may occur, and steps where employee and environmental hygiene are necessary to ensure the quality of the dietary supplement. These specifications are regulatory specifications addressed by these CGMP regulations. The final rule does not prevent you from establishing additional, nonregulatory specifications that are not at points, steps, or stages where control is necessary to ensure the quality of the dietary supplement. For example, you could establish specifications that largely address the appearance of the dietary supplement in an aesthetic sense. Such nonregulatory specifications are not addressed by the final rule.

(Comment 161) One comment notes that labelers would not be subject to proposed § 111.35(e).

(Response) Consistent with final § 111.1, persons who perform labeling operations are, in fact, subject to the final rule, including the requirements to establish specifications. As discussed in this section, the final rule includes an explicit requirement that, if you receive a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must establish specifications to ensure that the product that you receive is adequately identified and is consistent with your purchase order (final § 111.70(f)).

(Comment 162) One comment asks whether the manufacturer determines where control is ''necessary'' to prevent adulteration.

(Response) In accordance with the changes made to the section, the manufacturer does determine where control is necessary to ensure the quality of the dietary supplement.

(Comment 163) Some comments express concern that manufacturers who must confirm the validity of subjective criteria established as specifications may set the specifications as low as possible or set meaningless specifications.

(Response) The specifications you must establish under this final rule are designed to ensure the quality of the dietary supplement that you manufacture. It is not meaningless to establish requirements that will ensure, for example, the product meets the established specifications for identity, purity, strength, and composition, and is within specified limits on contaminants to prevent adulteration.

(Comment 164) Some comments express concern that the language of proposed § 111.35(e) may require specifications beyond those already required in the master manufacturing record, as stated in proposed § 111.45(a)(1), to identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration, or may require specifications for attributes that are not present at all stages. These comments urge us to be flexible during inspections as to what specifications are appropriate.

(Response) Final § 111.70(a) provides the manufacturer with flexibility in determining what specifications may be necessary for its operation. Moreover, final § 111.70(a) through (g) provide the manufacturer with flexibility to determine what the specifications require in order to ensure the quality of the dietary supplement.

2. Final § 111.70(b)

Final § 111.70(b) requires you to establish component specifications for each component you use in the manufacture of a dietary supplement. Under final § 111.70(b)(1), you must establish an identity specification for each component that you use in the manufacture of a dietary supplement. A specification for identity may include more than one attribute. For example, a specification for the identity of a salt used in the manufacture of a vitamin and mineral supplement may include the physical characteristics of the solid (e.g., as a crystal or as a powder), the color, and the state of hydration (e.g., with two or three molecules of water). A specification for the identity of a botanical may include the part of the plant (e.g., roots or leaves), the color, and whether the part of the plant is in a native state or has been ground. Under final § 111.70(b)(2), you must establish component specifications that are necessary to ensure that specifications for the purity, strength, and composition of dietary supplements manufactured using the components are met. Under final § 111.70(b)(3) you must establish limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement. Final § 111.70(b) derives from proposed § 111.35(e)(1) and (k). Final § 111.70(b) is consistent with comments, already discussed, that recommended the provisions of proposed § 111.35(k), regarding contaminants that could adulterate a product, be incorporated into proposed § 111.35(e). In addition, as discussed previously with respect to final § 111.55, final § 111.70(b) provides that the required component specifications you must establish for a dietary supplement include identity, purity, strength, and composition.

(Comment 165) A few comments state it is appropriate and acceptable to establish a requirement for a specification for the identity and purity of components, insofar as such specifications are necessary to ensure that components are not contaminated with substances having public health significance. However, these comments argue that specifications for quality, strength, and composition of components should only be required for the quality, strength, and composition that a component is purported to possess. One comment notes this would provide the same requirement that is currently established for drug products and processing. Some comments recommend that specifications should be established ''as appropriate'' or ''where control is necessary to assure production of a quality product.''

(Response) After considering the comments that questioned the need to establish specifications for the identity, purity, quality, strength, and composition of components, as well as the general comments that led to the overall approach that focuses on building quality into a dietary supplement at every stage of the production and process control system (see discussion in section IV of this document), we are requiring in final § 111.70(b)(1) that you establish an identity specification for components that you use. This identity specification is necessary to ensure that the finished dietary supplement meets its specification for identity because you could not know what your final product contains if you do not know what you put into it. In addition, final § 111.70(b)(2) requires you to establish those component specifications for purity, strength, and composition that are necessary to ensure that specifications for the purity, strength, and composition of dietary supplements manufactured using the components are met.

Final § 111.70(b)(2) provides flexibility for you to determine which component specifications other than identity are, or are not, necessary to

ensure that the final dietary supplement meets its specifications. For example, it is likely that you will need to establish a specification for the strength of vitamin C added as a component, that you use to make a multivitamin supplement, so that you will know how much vitamin C to add to satisfy the specification for the strength of the vitamin C in the final product. Thus, if you are manufacturing a vitamin C tablet with a strength of 50 milligrams (mg) per tablet, you must determine how much vitamin C, of a given strength, you must add in order to produce tablets that will contain 50 mg, after accounting for the theoretical yield at each step in the manufacturing process. However, you may not need to establish a specification for the strength of the tablet coating agent for that multivitamin supplement, if your final specifications include the amount of the tablet coating agent as part of the specifications for the composition, but not the strength of the multivitamin supplement. In most cases, a specification for the composition of the dietary supplement would be sufficient to ensure that the tablet coating agent is used within the established level.

(Comment 166) A few comments express concern about how to determine certain specifications for botanicals, such as the strength of peppermint leaf. The comments explain that a specification for strength of peppermint leaf could be based on a number of different attributes. One comment argues that establishing specifications for all dietary ingredients may not contribute to any assurance of product quality and will not protect public health. Some comments assert that ''quality, strength, and composition'' are subjective with respect to botanical ingredients for which no potency claim is made, and, thus, these attributes should not be included in the rule. Another comment asserts proposed § 111.35(e)(1) goes beyond either food or drug CGMPs and that the composition of approximately 1,200 botanicals used in the industry will be impossible to determine in an economically feasible manner.

(Response) To the extent that these comments assert that this final rule should not require you to establish specifications for the strength and composition of botanical ingredients, we disagree. As explained in response to comment 145, it is fundamental to CGMPs that you know what components are used to manufacture your dietary supplement and to ensure that the finished batch of dietary supplement contains the established identity, purity, strength, and composition. As explained in response to comment 40, this final rule does not require that you establish specifications for the identity, purity, strength, or composition of the various constituents that are inherently present in a natural product such as a botanical. However, as previously discussed in section VI of this document, depending on what you are manufacturing, the product specifications for the finished batch of a dietary supplement may include a specification, for example, of the strength of a substance that is present in the dietary supplement because it is a constituent of a natural product that you add as a component. For example, you may establish a specification for the amount of vitamin C in a dietary supplement that you manufacture by adding the component rose hips. If this is the case, then the component specifications for the natural product must include a specification for the strength of the constituent (e.g., vitamin C) in whatever amount you determine is necessary to meet the specification for the constituent (vitamin C) in the finished batch of dietary supplement.

(Comment 167) One comment asserts it would be more appropriate for proposed § 111.35(e)(1) to address components ''that you purchase'' than to address components ''that you receive,'' because customers sometimes provide the ingredient or product to be processed and the customer, rather than the manufacturer, establishes the specifications.

(Response) Final § 111.70(b) (derived from proposed § 111.35(e)(2)) requires that component specifications be established for each component that you use in the manufacture of a dietary supplement. Thus, the firm must establish specifications for the components it uses to manufacture a dietary supplement, regardless of whether it manufactures the components itself or contracts with another firm to manufacture the components. The firm that conducts the manufacturing operations, as explained in section VI of this document, would be responsible for complying with all relevant CGMP requirements in this final rule related to its operations.

(Comment 168) One comment asserts that proposed § 111.35(e)(1) is unnecessary because the requirements for testing to meet the manufacturer's specifications are described elsewhere.

(Response) We disagree. The requirements to establish specifications are distinct from what you must do to determine whether specifications are met. Under the final rule (§ 111.73), you have a responsibility to determine whether the established specifications are met. What criteria you must use in order to determine whether specifications are met are set forth in final § 111.75.

3. Final § 111.70(c)

Final § 111.70(c)(1) requires you, for in-process production, to establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplements and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement. Final § 111.70(c)(1) derives from proposed § 111.35(e)(2). Final § 111.70(c)(1) includes a nonsubstantive, editorial change that we are making for consistency with other regulations in part 111. This change is to refer to ''in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary'' rather than ''in-process controls in the master manufacturing record where control is necessary.''

We also have added that you must establish in-process specifications, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement. This clarifies that if it is necessary to establish limits on contaminants in-process, due to contamination that may occur in the facility you do so under final § 111.70(c)(1). With a requirement to set, as necessary, limits on contamination in-process, aspects of the production and process system from receipt to finished product are covered with respect to contamination. For example, under final § 111.70(e) you may determine that you need to establish a microbiological specification that the aerobic plate count of your finished batch of the dietary supplement will not exceed a certain number of colony forming units per gram of product. Under the written instructions in your master manufacturing record (final § 111.210(h)) and your written procedures for manufacturing operations (final § 111.353), you would establish controls to prevent microbial contamination at each point, step, or stage in the manufacturing process where control is necessary to prevent microbial contamination. To ensure that you will meet the microbiological specification that you set for the finished batch of the dietary supplement, you may determine that it is necessary to establish a specification

for the aerobic plate count at an intermediate stage of the in-process production.

Final § 111.70(c)(2) requires you, for in-process production, to provide adequate documentation of your basis for why meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the specifications are met for identity, purity, strength, and composition of the dietary supplements and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement. Final § 111.70(c)(3) requires that quality control personnel review and approve the documentation you provide under final § 111.70(c)(2). Final § 111.70(c)(3) also derives in part from proposed § 111.37(b)(1) which would require the quality control unit to approve or reject all processes that may affect the identity, purity, strength, or composition of a dietary supplement.

In final § 111.70(c)(2), we are requiring documentation that includes the basis for why meeting the in-process specifications, in combination with meeting the component specifications will help ensure the specifications for the identity, purity, strength, and composition of the dietary supplement and limits on contamination are met. Meeting in-process specifications alone may not ensure the identity, purity, strength, or composition of the dietary supplement, but information about the component specification may be needed in order to put the results from the in-process specification in perspective. For example, if the manufacturer establishes a component specification for lead that it not be greater than ''x'' mg and establishes a specification that all piping that comes into contact with the component be lead free in the facility, and there are no other components or equipment that would be a source of lead, then there should be no added lead from processing, provided that the material only came in contact with the lead-free pipes and only the other lead-free components and equipment are used. Thus, we would not know by looking solely at the in-process specification whether the lead in the final product is not greater than ''x'' mg. We would need to evaluate the component specification, in addition to the in-process specification, to ensure that the final product contains no greater than ''x'' mg lead. To emphasize the interplay of the specifications and component specifications in ensuring the specifications are met for the identity, purity, strength, and composition of dietary supplements, and, as necessary, for limits on contamination, final § 111.70(c)(1) and (c)(2) state ''help ensure'' rather then ''ensure'' the identity, purity, strength, and composition of dietary supplements and for limits on contamination.

(Comment 169) One comment asserts monitoring and process controls are more practical and effective than the proposed requirements for in-process testing, which the comment asserts are overly broad and could impose an undue burden on small businesses.

(Response) The comment's objection is unclear. The final rule requires that you establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary in the manufacturing process to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplement and, as necessary, for limits on contamination. You must monitor the in-process points, steps, or stages, where control is necessary to ensure the quality of the finished batch of dietary supplement, to determine whether the in-process specifications are met and to detect any deviation or unanticipated occurrence that may result in a failure to meet specifications (see final § 111.75(b)). The final rule does not establish specific requirements for in-process monitoring. The manufacturer must determine any in-process monitoring that is necessary to ensure that the specifications are met for the finished batch. Examples of such monitoring include measuring pH or viscosity.

4. Final § 111.70(d)

Final § 111.70(d) requires you to establish specifications for dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications). Final § 111.70(d) derives from proposed § 111.35(e)(4). Further, § 111.70(d) requires that packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of the dietary supplements, consistent with proposed § 111.35(e)(4). We deleted the phrase ''comply with other statutory and regulatory provisions'' from proposed § 111.35(e)(4) because the requirement was redundant to final § 111.5.

5. Final § 111.70(e)

Final § 111.70(e) requires you, for each dietary supplement that you manufacture, to establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement, all to ensure the quality of the dietary supplement. Final § 111.70(e) derives from proposed § 111.35(e)(3) and (k). Final § 111.70(e) is consistent with comments, already discussed, recommending that the provisions of proposed § 111.35(k) regarding contaminants that could adulterate a product be incorporated into proposed § 111.35(e).

6. Final § 111.70(f)

Final § 111.70(f) requires you, if you receive a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), to establish specifications to provide sufficient assurance that the product you receive is adequately identified and is consistent with your purchase order. Final § 111.70(f) derives from proposed § 111.35(e)(1) which would, in part, require you to establish specifications for dietary supplements that you receive. Final § 111.70(f) includes changes we are making after considering comments.

(Comment 170) One comment notes that labelers would not be subject to proposed § 111.35(e). Other comments request we clarify the roles of the various parties in the ''pre-consumer supply chain'' for dietary supplements. One comment suggests that manufacturers and packagers be responsible for establishing specifications only for the operations occurring in their own facility or for which they are otherwise responsible (e.g., subcontracted operations), not for upstream or downstream operations over which they may not have any control. This comment states that we intended to relieve packagers from establishing specifications for the dietary supplements that they package, and also states that such requirements should not be in the CGMP regulations.

(Response) We have discussed, in section VI of this document, who is subject to the final rule under § 111.1 in what the comment describes as the ''pre-consumer supply chain'' and do not repeat that discussion. We agree that packagers and labelers must establish specifications for the dietary supplements that they package and did not intend to relieve them of complying with relevant CGMP requirements. We recognize that a firm that only packages and labels a product may rely on

information about the content of the product that it receives from the manufacturer. The information may consist of an invoice, certificate, guarantee, or other form of verification as to what the product consists of so that the packager or labeler has adequate information about the dietary supplement it receives to label the product and to ensure that the product is consistent with its purchase order. Therefore, we are setting forth certain requirements that distinguish a product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) from a product you manufacture. One such requirement is final § 111.70(f) which requires you to establish specifications for a product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier).

The inclusion of final § 111.70(f), or any other provision that relates explicitly to a product you receive for packaging or labeling as a dietary supplement, does not alter the fact that such a product is no different from any other dietary supplement as far as the applicability of these CGMP requirements.

Under final § 111.70(f), the specifications you establish for a product you receive for packaging or labeling as a dietary supplement must provide sufficient assurance that the received product is adequately identified and is consistent with your purchase order. For example, you may be purchasing tablets that provide 500 mg (strength) (quantitative amount per serving) of vitamin C (identity). Therefore, your purchase order would need to include the identity and amount of vitamin C per tablet to distinguish it from other tablets of vitamin C that may contain only 60 mg, or from other vitamin tablets of 500 mg that you may also purchase.

Final § 111.70(f) sets forth a requirement for a product you receive for packaging or labeling as a dietary supplement that will be distributed by you, rather than returned to the firm from which you receive the product. Thus, § 111.70(f) applies to product that has left the control of the person who manufactured the batch.

If you are a packager or labeler who packages and labels for the manufacturer and you will return the packaged and labeled dietary supplement to the manufacturer, we would not consider that you are ''receiving'' product within the meaning of final § 111.70(f). Thus, you would not be subject to final § 111.70(f).

(Comment 171) Some comments assert that ''packaging'' should be included with ''manufacturing process,'' but that a firm involved only in ''holding'' a product should not have to set specifications.

(Response) Under final § 111.70(a), a person who holds packaged and labeled dietary supplements for distribution and who does no manufacturing, packaging, or labeling, would be required to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement. For example, a person may need to establish a specification for the temperature at which the product will be held. However, a person who only holds packaged and labeled dietary supplements for distribution is not required to establish component specifications (final § 111.70(b)), in-process specifications (final § 111.70(c)), specifications for labels and for packaging (final § 111.70(d)), product specifications (final § 111.70(e)), specifications for product received from a supplier for packaging as a dietary supplement (and for distribution rather than for return to the supplier) (final § 111.70(f)), or specifications for the packaging and labeling of the finished packaged and labeled dietary supplements (final § 111.70(g)) because the person does not engage in any of those activities. This is consistent with the views expressed by the comments regarding the applicability of proposed § 111.35(e) to persons who only hold packaged and labeled dietary supplements for distribution.

7. Final § 111.70(g)

Final § 111.70(g) requires you to establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements, including specifications that ensure you used the specified packaging and you applied the specified label.

Final § 111.70(g) is a new provision we are adding for clarity and consistency. We had proposed to require that you conduct a material review and make a disposition decision of any packaged and labeled dietary supplements that do not meet specifications (proposed § 111.70(c)). We proposed minimum standards for packaged and labeled dietary supplements—i.e., we would require that the quality control unit collect representative samples of each batch of packaged and labeled dietary supplements to determine whether you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record (proposed § 111.37(b)(11)(iv)). Final § 111.70(g) includes the minimum standards that we proposed to establish for packaged and labeled dietary supplements in proposed § 111.37(b)(11)(iv).

To make clear that the use of packaging and labels for a final packaged and labeled product must be that which is specified in the master manufacturing record, we have created a separate provision (under final § 111.70(g)) requiring you to create the relevant specifications to be met.

Final § 111.70(g) requires you to establish specifications that ensure you use the ''specified packaging'' and to apply the ''specified label'' as we proposed under proposed § 111.37(b)(11)(iv). We removed the words ''specified in the master manufacturing record'' as an editorial change that we are making to simplify the language of the requirement.

As already explained (see discussion of final § 111.70(a)), the specifications you establish under final § 111.70 are regulatory specifications required by these final CGMP requirements. The final rule would not prevent you from establishing additional, nonregulatory specifications, such as specifications that largely address the appearance of the dietary supplement in an aesthetic sense.

H. What is Your Responsibility for Determining Whether Established Specifications Are Met? (Final § 111.73)

Final § 111.73 requires you to determine whether all specifications you establish under final § 111.70 are met. The criteria for determining whether the specifications that you establish under final § 111.70 are met are set forth in final § 111.75. The oversight by quality control personnel for determining whether specifications established under final § 111.70 are met in accordance with the criteria established under final § 111.75 and under what conditions quality control personnel can approve deviations from specifications are set forth in final § 111.77 and final subpart F. Although final § 111.73 requires you to determine whether specifications are met, it is the responsibility of quality control personnel to conduct a material review and make a disposition decision if a specification established in accordance with final § 111.70 is not met.

Final § 111.73 derives, in part, from proposed § 111.35(f), (g), and (h). Final § 111.73 includes changes associated with reorganization, and other revisions associated with final § 111.70. Final § 111.73 neither includes any finished

batch testing requirements that derive from proposed § 111.35(g)(3) nor specifies what you must do to determine whether all specifications are met because the requirements for what means and methods you must use to determine whether specifications are met, including certain requirements for testing, are set forth in final § 111.75.

The comments relevant to final § 111.73 are the general comments that recommend an overall approach that focuses on building quality into a dietary supplement throughout the production and process control system. Because the primary focus of the relevant comments is on the proposed requirements for testing, we discuss those comments when we describe the derivation of the testing requirements in final § 111.75.

I. What Must You Do to Determine Whether Specifications Are Met? (Final § 111.75)

Final § 111.75 derives from proposed §§ 111.35(f), (g), (h), (k), and (l); 111.37(b)(11); and 111.40(a) and (b). Final § 111.75 describes the steps you must take to determine whether specifications are met.

(Comment 172) Many comments assert that the CGMPs for dietary supplements should place greater emphasis on in-process controls and HACCP principles. The comments state FDA's narrow focus on finished product testing is not in line with the philosophy of HACCP, in which manufacturing steps are controlled and verified so as to result in end products that are safe, with minimal finished product testing. One comment cites a 1997 document entitled ''Hazard Analysis and Critical Control Point Principles and Application Guidelines'' in which we state that ''[A]n effective HACCP system requires little end-product testing, since sufficient validated safeguards are built-in early in the process.'' (Ref. 31).

(Response) In the 1997 ANPRM, we asked for comments on whether certain, or all, of the requirements for manufacturing and handling dietary ingredients and dietary supplements may be more effectively addressed by a regulation based on the principles of HACCP, rather than the system outlined in the industry submission (62 FR 5700 at 5708). HACCP is a science-based, systematic approach to preventing food safety problems by anticipating how such problems are most likely to occur and by installing effective measures to prevent them from occurring. The HACCP concept is a systematic approach to the identification and the assessment of risk (likelihood of occurrence and severity), and control of the biological, chemical, and physical hazards associated with a particular food production process or practice. HACCP is a preventive strategy. It is based on development by the food producer of a plan that anticipates food safety hazards and identifies the points in the production process where a failure would likely result in a hazard being created or allowed to persist; these points are referred to as critical control points (CCPs).

Under HACCP, identified CCPs are systematically monitored, and records kept of that monitoring. Corrective actions are taken when control of a CCP is lost, including proper disposition of the food produced during that period, and these actions are documented. Thus, the focus of a HACCP-based approach is to anticipate food safety hazards, take actions to prevent them, and keep records of both the actions taken to prevent problems and the actions taken if a problem nonetheless occurs.

As discussed in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12174), most of the comments that we received to the ANPRM opposed basing a CGMP regulation for dietary supplements on HACCP principles. Consistent with those comments, we proposed certain requirements that, although consistent with a HACCP-based approach, did not require a HACCP-based approach. For example, proposed § 111.65 would establish requirements for manufacturing operations, including several proposed requirements to prevent contamination of components or dietary supplements, but would not require that you develop a specific plan for the precautions that you would take, or that you keep records of any monitoring that was directed solely at preventing specific types of contamination.

In contrast to the specific focus of HACCP to anticipate food safety hazards, take actions to prevent them, and keep records of both the actions taken to prevent problems and the actions taken if a problem nonetheless occurs, CGMP requires that you take all necessary steps to both prevent hazards and ensure that the product that you manufacture is what you established in your specifications. The proposed testing requirements were directed at ensuring that a dietary supplement meets all of its established specifications, including specifications for the identity, purity, strength, and composition, rather than on ensuring only that specific food safety hazards that you take steps to prevent are not, in fact, present in the dietary supplement. The comments that assert that the CGMP requirements should place greater emphasis on HACCP principles and, in so doing, reduce the requirements to test product at the finished batch stage, did not explain how the preventive measures that are associated with a HACCP plan would be effective at ensuring that a dietary supplement is what you established it to be in your specifications. Therefore, we are not, as the comments request, including additional HACCP requirements as part of the overall approach set forth in this final rule.

In the 2003 CGMP Proposal, we noted that you may voluntarily choose to implement a HACCP plan that meets the requirements of the National Advisory Committee on Microbiological Criteria for Foods, but that proposed part 111 would still apply to you (68 FR 12157 at 12174). We also noted that any HACCP plans that are intended to meet the records requirements under proposed part 111 would be treated as records under the CGMP regulations.

(Comment 173) One comment states that it supports a requirement that a firm ensure that specifications have been met and asserts that the 2003 CGMP Proposal failed to do so. This comment asserts the specific testing requirements in proposed § 111.35(g)(1) and (g)(2) must be significantly modified and suggests that a more effective approach would be to establish separate requirements for ensuring that specifications are met in each of the four categories addressed by proposed § 111.35(e): Goods received (§ 111.35(e)(1)), in-process controls (§ 111.35(e)(2)), manufactured goods (§ 111.35(e)(3)), and labels and packaging (§ 111.35(e)(4)).

(Response) The final rule is consistent with this comment. Final § 111.70 requires you to establish certain specifications (including specifications for components, in-process controls, the finished batch and packaging and labels), and final § 111.75 sets forth the requirements for what you must do to determine whether those specifications are met.

1. Final § 111.75(a)

Final § 111.75(a)(1) requires you, before you use a component that is a dietary ingredient, to conduct at least one appropriate test or examination to verify the identity of the dietary ingredient. We recognize, however, that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would provide no material diminution

of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we decided to provide, in an interim final rule published elsewhere in this issue of the **Federal Register**, a procedure that allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met.

Final § 111.75(a)(2) requires you, before you use a component, to confirm the identity of other components and determine whether other applicable component specifications established in accordance with § 111.70(b) are met. To do so, final § 111.75(a)(2) requires you to either conduct appropriate tests or examinations (final § 111.75(a)(2)(i)); or rely on a certificate of analysis from the suppler of the component that you receive (final § 111.75(a)(2)(ii)). Final § 111.75(a)(2)(ii) sets forth the criteria that you must satisfy in order to rely on a certificate of analysis from a supplier:

- You must first qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations;
- The certificate of analysis must include a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations;
- You must maintain documentation of how you qualified the supplier;
- You must periodically re-confirm the supplier's certificate of analysis; and
- Quality control personnel must review and approve the documentation setting forth the basis for qualification (and re-qualification) of any supplier.

Final § 111.75(a)(1) and (a)(2) derive, in part, from proposed § 111.35(g) and (h) and proposed § 111.40(a)(2) and (a)(3). Final § 111.75(a)(1) and (a)(2) include changes that we are making after considering comments to proposed §§ 111.35 and 111.40(a).

(Comment 174) Many comments assert that a certificate of analysis from a properly certified supplier can be a key element of the manufacturing process, and reduce the need for testing at the finished batch stage. Some comments specifically recommend the dietary supplement manufacturer conduct identity tests to ensure that the correct component has been received (also, see comment 145 of this document).

Some comments recommend an appropriate vendor qualification program, including a combination of vendor audits and product testing, to alleviate the need for complete testing of every lot of incoming components.

Several comments stress that a meaningful certificate of analysis must be based on the results of actual analytical testing. One comment adds that reliance on a supplier's certificate of analysis should be conditioned on a qualification program whereby the recipient independently verifies the supplier's ability to conduct tests and verifies test results through confirmatory testing.

Many comments provide suggestions for ways in which manufacturers could demonstrate the reliability of a certificate of analysis, which include the following: (1) Identity testing of ingredients and components, (2) maintenance of documentation of appropriate test results, (3) appropriate verification of the information provided initially and at appropriate intervals, and (4) documentation that any suppliers have adequate CGMP programs in place.

Some comments recommend that vendor certification programs include plant visits and inspections, while other comments do not believe manufacturers should be required to conduct plant inspections. Other comments recommend that vendor certification programs include CGMP audits or process reviews at supplier facilities; verification of laboratory test results against a certificate of analysis; and 100 percent inspection and testing of incoming materials for a specified period of time while reliability is being assessed.

Some comments provide suggestions for the types of information that should be included on an acceptable certificate of analysis, such as moisture, sieve analysis, identity, and results of tests against established raw material specifications and specifications of any compendia referenced on the label. One comment suggests that a certificate of analysis could be converted into sworn affidavits to guarantee their reliability. Some comments suggest that a system of testing one batch for agreement with the certificate of analysis, and then relying on this information for future purchases, would work well if the suppliers are required to provide reliable and valid certificate of analysis documents. One comment suggests we issue guidelines as to what should be included in a properly verified certificate of analysis.

Some comments address the requirement in proposed § 111.40(a)(2) to ''Visually examine the suppliers invoice, guarantee, or certification * * * and perform testing, as needed, to determine whether specifications are met.'' One comment agrees with this proposed requirement and asserts that the supplier's certification is not sufficient to ensure that appropriate standards are met. Other comments, however, disagree with this aspect of the proposed requirement or ask for further clarification. A few comments assert that manufacturers should not have to retest material already tested by a supplier. Some comments note that a certificate of analysis can be used for ensuring received materials are consistent with the purchase order, and assert the certificate of analysis can be an appropriate way to ensure specifications are met without requiring testing. One comment suggests the phrase ''perform testing, as needed'' be replaced with ''perform testing, if necessary'' and that the CGMP regulations allow for the use of a certificate of analysis that has been verified through a vendor certification process. Another comment states that the provisions requiring testing in proposed § 111.40(a)(2) are more burdensome than those required of food and pharmaceutical products and cites the drug CGMP provision that permits the use of certificates of analysis in lieu of testing for conformity with written specifications. One comment supports the idea of testing upon receipt in the specific circumstance when testing cannot be performed on the finished product.

Several comments contend that there is a conflict between the 2003 CGMP Proposal and our position during our stakeholder meetings. The comments assert that, at the meetings, FDA representatives recognized that a verified certificate of analysis is acceptable, provided it is based on appropriate testing from suppliers who are audited by their customers as to their testing and manufacturing practices.

A few comments say the 2003 CGMP Proposal should allow more reliance on strict chain of custody and documentation requirements. Other comments recommend that manufacturers not be required to retest previously tested incoming ingredients if they arrive with the vendor's seal intact. Rather, the purchaser should be able to rely on the vendor's test results, as presented in a verified certificate of analysis, unless there has been a breach in quality control during distribution and subsequent manufacture. One

comment notes the Canadian regulations for Natural Health Products allow periodic testing of ingredients if a manufacturer has satisfactory evidence that the raw materials sold to him/her are consistently manufactured in compliance with established specifications.

(Response) We agree that CGMP requires that a person who manufactures a dietary supplement conduct at least one appropriate test or examination to verify the identity of each dietary ingredient that will be used in the manufacture of the dietary supplement. For example, because some botanicals require microscopic examination and comparison to a reference to be distinguished, and because suppliers of such botanicals may manufacture several of these botanicals, it is important to verify that a botanical that you receive from a supplier is the correct botanical. In some cases, a single test or examination may be all that is needed to verify the identity of a dietary ingredient; in other cases, it may be necessary to conduct more than one test or examination. It is the responsibility of the manufacturer to determine the appropriate test(s) or examination(s) necessary to verify the identity of a dietary ingredient.

The comments discussed the importance of testing all components for identity and did not appear to limit their recommendation for conducting identity tests to those components that are dietary ingredients. Based on the comments, we conclude that many firms would conduct an identity test for most ingredients and other components rather than limit identity testing to dietary ingredients. However, because dietary ingredients are the central defining ingredient of a dietary supplement, final § 111.75(a) only requires you to conduct tests or examinations to verify the identity of any component that is a dietary ingredient. As discussed previously in this section, we recognize, however, that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would provide no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we decided to provide, in an interim final rule published elsewhere in this issue of the **Federal Register**, a procedure that allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. For components other than dietary ingredients you must confirm the identity of the component and you have the flexibility of relying on a certificate of analysis, in lieu of conducting a test or examination, to confirm identity. The preamble to the 2003 CGMP Proposal discussed why we were not proposing that you could rely on a certificate of analysis, but did not express a view as to whether the establishment of minimum criteria for how you would qualify the supplier, and for what must be included on the certificate of analysis, could alleviate our concerns about whether the certificate of analysis could ensure certain attributes of dietary supplements.

After considering the comments, we also are persuaded that it is possible to rely on a certificate of analysis from the supplier, for attributes other than identity of the dietary ingredient, provided you satisfy certain minimum criteria set forth in final § 111.75(a)(2)(ii). These criteria include qualifying the supplier, maintaining documentation of how you qualified the supplier, periodically reconfirming the supplier's certificate of analysis, and having quality control personnel review and approve the documentation setting forth the basis for qualifying the supplier. These criteria also require that the certificate of analysis, at a minimum, includes a description of the test or examination method(s) used, limits of the tests or examinations, and the actual results of the tests or examinations. Under final § 111.75(a)(2)(ii)(A), to qualify the supplier you must establish the reliability of the supplier's certificate of analysis through confirmation of the supplier's tests or examinations.

Certain comments request that we provide guidance on what should be included in a certificate of analysis. As stated earlier in this section, a certificate of analysis is a document, provided by the supplier of a component prior to or upon receipt of the component, that documents certain characteristics and attributes of the component. Instead of guidance, we are establishing, in final § 111.75(a)(2)(ii)(B), minimum criteria that a certificate of analysis must meet to satisfy these CGMP requirements. As we gain experience in applying the CGMP regulations, we will consider whether it is appropriate to provide guidance on certificates of analysis.

(Comment 175) One comment asks if a raw material contains an unknown amount of excipients, is it necessary to quantify the excipients or can a company simply assess the active material and rely on a vendor's specification for the excipient content?

(Response) To the extent that this comment is asking whether it is necessary to set a component specification for the strength of excipients that are present in a dietary supplement, the final rule does not require you to do so provided that such a component specification is not necessary to ensure that the specifications for the purity, strength, composition, or contamination limit for the dietary supplement manufactured using the excipients are met (final § 111.70(b)(2)). If such a strength specification for an excipient is necessary to ensure that the purity, strength, or composition specifications are met, or that a contamination limit is met for the dietary supplement, you could, as the comment suggested, rely on a certificate of analysis for that quantitative information provided that you satisfy the criteria set forth in final § 111.75(a).

2. Final § 111.75(b)

Final § 111.75(b) requires that you monitor the in-process points, steps, or stages where control is necessary to ensure the quality of the finished batch of dietary supplement, to determine whether the in-process specifications are met, and to detect any deviation or unanticipated occurrence that may result in a failure to meet specifications. Final § 111.75(b) derives from proposed § 111.35(f) with revisions associated with final § 111.70(c)(1).

(Comment 176) A few comments argue that it is not possible to monitor in-process for those specifications required under proposed § 111.35(e). One comment states that a specification such as identity is no longer identifiable at an in-process stage. This comment also notes any such requirement in proposed § 111.35(e) would be redundant, because proposed § 111.35(h) requires a firm to ensure, through testing or examination, that all established specifications are met. Another comment contends that some specifications are not met until processing is complete, such as with liquid extracts. A few comments recommend that the requirement for monitoring be limited to ensuring that specifications established for in-process controls under proposed § 111.35(e)(2) and finished product under proposed § 111.35(e)(3) are met.

One comment states it is not always possible for a manufacturer to monitor for strength and purity of raw materials during in-process steps. The comment suggests this proposed requirement be removed or revised.

(Response) The comments may have misunderstood what we refer to as ''in-process'' specifications. Under final § 111.75(b), you must monitor the in-process points, steps, or stages where control is necessary to ensure the quality of the finished batch of dietary supplement, to determine whether the in-process specifications are met, and to detect any deviation or occurrence that may result in a failure to meet specifications. The in-process specifications that you establish ensure that, for example, the specification for strength is achieved. If you must deliver a certain amount of powdered vitamin C to a mixture at a certain point in the process in order to achieve a final product that contains 60 mg of vitamin C, a critical point in the process is where ''x'' mg of vitamin C is added to ensure that the final product contains 60 mg of vitamin C. You would monitor the operation to ensure that ''x'' mg of vitamin C is added. Your strength specification may be tested at the end of the process as a product specification, but your in-process specification to ensure the addition of ''x'' mg of vitamin C is a specification that is separate and distinct from the specification that you establish for strength, i.e., 60 mg vitamin C. You may determine that in-process specifications are met through a test or examination. You could monitor for the vitamin C product by checking the equipment you use to mix the vitamin C-containing product to ensure that the mixing process was carried out during the time period specified in the master manufacturing record to ensure uniformity in the finished batch. Other examples could include a measurement, such as checking pH during the course of a process, or removing samples during the course of a process to conduct a test for viscosity. There may be no need for certain in-process specifications to ensure that specifications for identity, purity, strength, and composition of the finished batch of dietary supplement are met. If there are no in-process points, steps, or stages at which any test or examination is needed to ensure that the identity specification for the finished batch of dietary supplement is met, then you would not need to establish an in-process specification to ensure identity in the finished batch, and, therefore, would not need to conduct in-process monitoring for identity.

(Comment 177) One comment requests clarification on what would be considered ''in-process'' for materials that are simply blended together to form a final product. The comment asks how a firm would test the samples if a final material cannot be tested due to interferences or lack of an available method.

(Response) Examples of in-process specifications when materials are simply blended together are the mixing time and speed.

(Comment 178) One comment points out that in-process testing for ''unanticipated occurrences'' required under proposed § 111.35(f) would be difficult, because the manufacturer would not know what to test for.

(Response) This comment may have misunderstood the provision, which did not propose to require that you test for an unanticipated occurrence. Rather, proposed § 111.35(i)(2) would require you to review the results of any monitoring, and conduct a material review and make a disposition decision, if there is any unanticipated occurrence that adulterates or could result in adulteration of a component or dietary supplement. An example of such an occurrence is leakage of extraneous material from a pipe onto a component. Quality control personnel, under final § 111.113(a)(3), must conduct a material review and make a disposition decision if there is such an unanticipated occurrence during the manufacturing operations.

(Comment 179) One comment suggests that the provision is a HACCP requirement and is unnecessary for dietary supplements whose production generally does not involve bacterial contamination.

(Response) We disagree. It is not a HACCP requirement because the provisions deal with unanticipated occurrences. Dietary supplement production can involve bacterial contamination as discussed in section V of this document. The purpose of final § 111.75(b) is to ensure that the product meets all specifications, which include specifications associated with contamination, and, therefore, is a necessary provision.

3. Final § 111.75(c) and (d)

Final § 111.75(c) requires you, for a subset of finished dietary supplement batches, which you identify through a sound statistical sampling plan (or for every finished batch), to verify that your finished batch of the dietary supplement meets product specifications for identity, purity, strength, composition, and limits on those types of contamination that may adulterate or that may lead to adulteration of the finished batch of the dietary supplement. Final § 111.75(c) also sets forth the following verification requirements:

- You must select one or more established specifications for identity, purity, strength, composition, and limits on those types of contamination that may adulterate or that may lead to adulteration of the dietary supplement that, if tested or examined on the finished batch of the dietary supplement, would verify that the production and process control system is producing a dietary supplement that meets all product specifications (or only those product specifications not otherwise exempted from this provision by quality control personnel under final § 111.75(d));
- You must conduct appropriate tests or examinations on the specifications selected in final § 111.75(c)(1);
- You must provide adequate documentation of your basis for why meeting the specification(s) selected under final § 111.75(c)(1), through the use of appropriate tests or examinations conducted under final § 111.75(c)(2), will ensure that your finished batch of the dietary supplement meets all product specifications for identity, purity, strength, composition, and the limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the dietary supplement; and
- Quality control personnel must review and approve the documentation that you provide under final § 111.75(c)(3).

Final § 111.75(c) requires you to verify that your finished batch of dietary supplement meets specifications for identity, purity, strength, composition, and limits that you established for those types of contamination that may adulterate or that may lead to adulteration of the finished batch. You may verify this by either testing or examining: (1) Every finished batch for each of these specifications or (2) a subset of finished batches for the dietary supplement. The subset of batches tested must be identified using a sound statistical sampling plan.

If you choose to test or examine a subset of finished batches of dietary supplement, you may test or examine each subset of batches for identity, purity, strength, composition, and limits on contamination that you established. Alternatively, you may determine that you can select one, two, or three, or other number of these specifications that, if determined to be in compliance

with specifications, would be able to verify that the other untested specifications are met. For example, you may be able to substantiate that, if you determine compliance with the specification for the identity and composition of a product for which no contamination limits are needed, the system is adequately controlling for the purity and strength of the product, without the need to test for compliance with the specifications for purity and strength. If so, you must document, under final § 111.75(c)(3) your basis for why this is so. Quality control personnel must review and approve such documentation under final § 111.75(c)(4).

Under final § 111.75(d), you may determine, in the previous example, that you could not verify, by testing for compliance with the specifications for identity and composition, that the purity specification is met, and there may be no scientifically valid method for testing or examining the finished batch to evaluate the purity in the finished batch of dietary supplement. In that case, you could exempt the specification for purity from the requirement in final § 111.75(c)(1) if you can document why the purity specification is met without such testing or examination. You could do so through, for example, documentation that meeting component and specifications for strength is sufficient, or through documentation that in-process monitoring is sufficient. Quality control personnel must review and approve such documentation (final § 111.75(d)).

Final § 111.75(c) and (d) derive from proposed § 111.35(g) and (h) and include changes that we are making after considering comments.

(Comment 180) Several comments assert that a more appropriate balance is needed between an effective process control system and a reasonable testing scheme calculated to confirm the quality of dietary supplements. The comments stress it is important to build quality into a product throughout the entire production process by relying on strong process controls rather than by testing at the finished batch stage. One comment asserts that in an appropriate process control system, testing is a means to monitor and ensure that the control system is functioning as intended. Several comments make a specific recommendation that the final rule include rigorous controls.

Some comments support the requirement under proposed § 111.35(g) to test each batch of finished product when possible, and to perform testing of components and in-process testing when testing the finished product is not possible. Other comments object to the proposed requirements for finished product testing on the grounds that they are overly burdensome, duplicative, and unnecessary.

Some comments suggest that a more practical approach to finished product testing would be to conduct identity testing of each component, combined with certification of the vendor by a program of complete testing for conformance with a certificate of analysis, as is allowed under the drug CGMP regulations. Some comments suggest manufacturers that have written procedures for each stage of their process, including raw material certification, production, and finished product analysis, and a written plan for qualifying the process, should be exempt from the proposed requirements to test each finished batch. Some comments urge us to give companies the flexibility to devise testing procedures.

(Response) The approach in final § 111.75(c) and (d) is consistent with these comments and is part of the overall approach of this final rule, which focuses on ensuring the quality of the dietary supplement throughout the production and process control system.

The concept behind final § 111.75(c) and (d) is analogous to the overall concept of proposed § 111.35(g). Under proposed § 111.35(g) you could rely on a combination of meeting component specifications and in-process specifications when you are unable to test for a specification, provided you satisfied certain criteria. Under the final rule, you may rely on a combination of meeting component specifications and in-process specifications to verify that your product meets specifications, rather than test every batch to determine whether specifications are met, regardless of whether a test is available, provided you satisfy certain criteria. Thus, the final rule provides flexibility that is needed to build adequate controls early in the process to reduce the need for end product testing on every batch of finished dietary supplement.

(Comment 181) One comment expresses concern that the requirement to use appropriate tests to determine compliance with specifications could be interpreted as requiring companies to test dietary supplements not only for compliance with company specifications, but also for compliance with any labeled specifications of the ingredient suppliers, such as for contaminants. The comment believes this would be redundant and overly burdensome.

(Response) As we explain in section XXIV of this document, we have made changes to reduce the testing burden on companies while still requiring steps necessary to ensure the quality of dietary supplements. For example, under final § 111.75(a), instead of testing or examination (other than for identity of the dietary ingredients), firms may rely upon supplier certificates of analysis in certain circumstances. Also, we recognize, however, that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would provide no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we decided to provide, in an interim final rule published elsewhere in this issue of the **Federal Register**, a procedure that allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. In addition, under final § 111.75(c), testing or examination for a portion of the finished batches is an option, and exemptions are provided for in final § 111.75(d).

(Comment 182) One comment points out that, if a product cannot be tested for technical reasons at the final product stage, then it also cannot be tested at the final blending stage in the process, because the nature and composition of the product at both stages are virtually the same. Another comment asks whether a verification of content in the final product will suffice if there is no valid testing procedure.

(Response) Under final § 111.75(c), you have flexibility to select one or more established specifications for identity, purity, strength, composition, and limits on those types of contamination that may adulterate or that may lead to adulteration of the dietary supplement that, if tested or examined on the finished batch of the dietary supplement, would verify that the production and process control system is producing a dietary supplement that meets all product specifications. Under final § 111.75(d), you have flexibility to exempt one or more product specifications from verification requirements, provided that

you satisfy the criteria established under final § 111.75(d).

(Comment 183) Some comments request that the rule include requirements for dissolution, disintegration, and bioavailability testing for dietary supplements. These comments note that, although a product may contain the labeled amount, it may not dissolve readily in the body or be available for absorption.

(Response) We decline to revise the rule as suggested by the comments. As discussed in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12163), tests for dissolution, disintegration, and bioavailability of dietary supplements are examples of areas where scientific study is still evolving; thus it is premature to impose requirements for such tests. The comments provide no specific information that would alter this view or support the technical feasibility of conducting such tests for all types of dietary supplement products. However, nothing in this final rule would preclude a manufacturer from establishing such requirements. A manufacturer should have data to support any specifications it establishes for parameters such as dissolution, disintegration, and bioavailability.

(Comment 184) One comment questions the requirements in the 2003 CGMP Proposal that all manufacturers quantify certain marker compounds in their products. The comment offers two reasons why such testing should not be required for botanical products: Their food-like composition and legal status, and the assertion that scientifically valid analytical methods may prove to be irrelevant or even hinder the development of superior products.

(Response) The final rule does not require any specific testing requirements, such as testing for marker compounds. You would determine the specific testing requirements, and whether to use a marker compound in those tests, depending on your product and process. In the 2003 CGMP Proposal (68 FR 12157 at 12172), we merely discussed how a marker compound could help you identify whether you have a particular species of an herb to differentiate, for example, between a poisonous and nonpoisonous species.

4. Final § 111.75(e)

Final § 111.75(e) requires you, before you package or label a product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), to visually examine the product and have documentation to determine whether the specifications that you established under final § 111.70(f) are met. Final § 111.75(e) derives from proposed § 111.35(e)(1) and (g) and from proposed § 111.40(a)(2).

(Comment 185) Some comments request we clarify the roles and testing obligations of the various parties in the ''pre-consumer supply chain'' for dietary supplements. Some comments argue that redundant tests should not be required at every transaction point in the pre-consumer supply chain. The comments contend that any testing already performed by a supplier, manufacturer, or packager should suffice, so long as other CGMP certification, and chain of custody standards, are met. Other comments urge us to give companies the flexibility to devise testing procedures and point out that different testing is needed for different roles in the supply chain.

One comment requests clarification of the testing requirements applicable to packagers/labelers. The comment states it is unclear how a packager or labeler/distributor could conduct testing of component ingredients if all the firm receives is a finished product for which there is no scientifically valid testing method.

(Response) As discussed in section VI of this document, you are responsible for the CGMP requirements that are applicable to your operations. We agree that redundant tests should not be required. Further, we agree that it is the responsibility of the manufacturer to do component testing. The packager or labeler does not need to do any required component testing because the packager or labeler does not receive components, rather it receives a finished dietary supplement. Under final § 111.70(f) if you receive a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must establish specifications to provide sufficient assurance that the product you receive is adequately identified and is consistent with your purchase order.

Under final § 111.75(e), before you package or label such a product, you must visually examine the product and have documentation to determine whether the specifications that you established under final § 111.70(f) are met. Your documentation may consist of an invoice, certificate, guarantee, or other documentation from the supplier to ensure that the product is adequately identified and is the product that you ordered. Final § 111.75(e) does not require that the documentation consist of the result of testing or examination by the packager or labeler of such a product.

As with final § 111.70(f), final § 111.75(e) applies to ''product that you receive for * * * for distribution rather than for return to the supplier'' and, thus, applies to product that has left the control of the person who manufactured the batch. If you are a packager or labeler who packages and labels a dietary supplement for the manufacturer, and you will return the packaged and labeled dietary supplement to the manufacturer, we would not consider that you are ''receiving'' product within the meaning of final § 111.75(e). Thus, you would not be subject to final § 111.70(f).

5. Final § 111.75(f)

Before you use packaging, final § 111.75(f)(1) requires you, at a minimum, to conduct a visual identification of the containers and closures and review the supplier's invoice, guarantee, or certification to determine whether packaging specifications are met. Before you use labels, final § 111.75(f)(2) requires you, at a minimum, to conduct a visual examination of the label and review the supplier's invoice, guarantee, or certification to determine whether labeling specifications are met. Final § 111.75(f)(1) and (f)(2) derive from proposed § 111.40(b)(2) which, in part, would require you, for packaging and labels you receive, to conduct at least a visual identification on the containers and closures. Proposed § 111.40(b)(2) also would require you, in part, for packaging and labels you receive, to quarantine the packaging and labels until your quality control unit tests or examines a representative sample to determine whether specifications are met. Consistent with changes that we are making to the requirements for packaging and labels that you receive (see discussion of final § 111.160 in section XII of this document), final § 111.75(f)(1) and (f)(2) include a requirement analogous to proposed § 111.40(a)(2) which would require you to visually examine the supplier's invoice, guarantee, or certification to determine whether the components, dietary ingredients, or dietary supplements you receive are consistent with your purchase order and to perform testing, as needed, to determine whether specifications are met.

6. Final § 111.75(g)

Final § 111.75(g) requires you, at a minimum, to conduct a visual examination of the packaging and labeling of the finished packaged and labeled dietary supplements to determine whether you used the specified packaging and applied the specified label. Final § 111.75(g) derives from proposed § 111.37(b)(11)(iv) which

would require the quality control unit to collect representative samples of each batch of packaged and labeled dietary ingredients or dietary supplements to determine whether you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record. Final § 111.75(g) is associated with final § 111.70(g) which requires you to establish specifications for the packaging and labeling for the finished packaged and labeled dietary supplements, including specifications that ensure you used the specified packaging and applied the specified label.

7. Final § 111.75(h)

Final § 111.75(h)(1) requires you to ensure that the tests and examinations you use to determine whether the specifications are met are appropriate and scientifically valid methods. Final § 111.75(h)(1) derives from proposed § 111.35(h). Final § 111.75(h)(1) includes editorial changes associated with the reorganization and changes that we are making after considering comments.

Final § 111.75(h)(2) requires that the tests and examinations you use include at least one of the following: Gross organoleptic analysis, macroscopic analysis, microscopic analysis, chemical analysis, or other scientifically valid methods. Final § 111.75(h)(2) derives from proposed § 111.35(l).

(Comment 186) Some comments suggest that the tests listed in proposed § 111.35(l) be incorporated into proposed § 111.35(h), relating to appropriate test methods.

(Response) We agree with the comment, and final § 111.75(h)(2) combines these requirements as requested.

(Comment 187) One comment states that the list of tests should be deleted because it is not sufficient to cover the types of testing that will be required for compliance with proposed § 111.35(g).

(Response) The comment does not identify the types of tests that would not be covered. We believe that final § 111.75(h)(2)(v)'s ''catch-all'' provision, which requires that one of the tests that you use be an ''other scientifically valid method'' is sufficient to cover all other types of testing required under this final rule.

(Comment 188) One comment states that the final rule should make clear that organolepsis is an acceptable method for identity testing. The comment contends it is imperative for the survival of small businesses that organolepsis be allowed, coupled as necessary with macroscopic and morphological examination and comparison with voucher specimens or photographs. Another comment requests clarification of whether gross organoleptic analysis alone can be a test for releasing finished products. Some comments assert that several organizations have published relevant methods that include macroscopic methods that can be used in identifying herbal ingredients.

(Response) Organolpetic analysis would be an acceptable method under the 2003 CGMP Proposal and remains an acceptable method under the final rule, which clarifies that the method you use, including organoleptic analysis, must be appropriate. Organoleptic analysis may not be an appropriate method of testing for certain substances. This is particularly true when the nature of the substance decreases the reliability of organoleptic analysis. For example, while organoleptic analysis may be an appropriate identity test for whole or coarsely-cut botanical parts, it may not be an appropriate identity test for powdered or extracted botanicals because of decreased reliability, or in those instances where misidentification of botanicals is known to occur. Additionally, we recognize ''macroscopic analysis'' is one of the tests or examinations you may select to determine whether specifications are met.

(Comment 189) One comment remarks that the appropriateness of the test depends on the material being tested, and the method selected by the manufacturer may be inappropriate. One comment believes the methods stated in proposed § 111.35(l) (organoleptic, microscopy, chemical) for establishment of identity and purity would not be applicable to animal products. This comment suggests that a separate list of test methods should be identified for those materials.

(Response) We agree that the appropriateness of the test depends on the material being tested. However, we are not revising the rule to identify methods that are, or are not, appropriate for specific circumstances (such as the case of animal-derived ingredients). There are so many distinct circumstances that such a list would be neither practical nor useful. Beyond that, the manufacturer is responsible for choosing the appropriate test.

(Comment 190) One comment asks us to clarify in the final rule the requirement that methods be scientifically valid applies only to quantitative methods.

(Response) In proposed § 111.35(h), we did not intend that the proposed requirement that you use scientifically valid methods apply only to quantitative methods, because we also proposed that tests in accordance with proposed § 111.35 must include at least one of the following: (1) Gross organoleptic analysis, (2) microscopic analysis, (3) chemical analysis, or (4) other appropriate test. To clarify that the requirement that methods be scientifically valid applies to all the tests and examinations you use, rather than to quantitative tests alone, final § 111.75(h)(1) does not use the term ''analytical.''

(Comment 191) One comment states that the proposed definition of ''appropriate test'' (i.e., ''a scientifically valid analytical method'') is extremely onerous and violates congressional intent. The comment believes that mandating specific methods is inappropriate, and dietary supplement CGMPs should comply with Executive Order 12866 and not impose additional requirements on small businesses that are better left to normal business practices.

Several comments take issue with our statement that we were not aware of a situation where an appropriate scientifically valid method is not available when, in fact, valid test methods are not always available for testing dietary ingredients or dietary supplements. One comment contends the 2003 CGMP Proposal contains conflicting information about available test methods. For example, the preamble to the 2003 CGMP Proposal states that we are ''not aware of a situation where an appropriate scientifically valid analytical method is not available,'' and our cost analysis does not address costs of method development. At the same time, however, we set out alternatives to finished product testing in cases where adequate methods are unavailable, and we decline to require expiration dating because there may not be adequate methods available for assessing the strength of a dietary ingredient. The comment cites numerous ongoing efforts in methods development by both industry and government that illustrate the lack of existing methods necessary to confirm compliance with all quality specifications.

(Response) These comments appear to take our statements out of context. In the 2003 CGMP Proposal, we stated: ''If an AOAC or FDA method is not available, a scientifically valid analytical method is one that is based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research. Although there may not be an Association of Official Analytical

Chemist (AOAC) or FDA method available, we are not aware of a situation where an appropriate scientifically valid analytical method is not available'' (68 FR 12157 at 12198). We also stated: ''We recognize that certain tests for identity, purity, quality, strength, or composition for certain finished product may not be available due to complex finished matrices that would make such testing impracticable'' (68 FR 12157 at 12197). We disagree that our statement acknowledging that the available tests may not be practicable in certain matrices is inherently inconsistent with our statement that we are not aware of a situation where an appropriate scientifically valid analytical method is not available. One statement relates to the availability of methods, the other relates to the practicality of using an available method in particular circumstances.

In any case, under final § 111.75(d)(1) you may exempt a product specification from the verification requirements of final § 111.75(c)(1) if you show that: (1) The specifications selected to verify that the product meets all product specifications are not able to verify that the control system is producing a dietary supplement that meets the exempted product specification and (2) there is no scientifically valid method for testing or examining the exempted product specification at the finished batch stage. Final § 111.75(c)(1) also requires you to document why other information, such as component and in-process testing, will determine whether the exempted product specification is met without finished batch testing. Although we agree that there may be some circumstances where there is not a scientifically valid method available for finished product testing, we believe that there would be some scientifically valid method available for component or in-process testing.

(Comment 192) One comment encourages flexibility toward the development of a quality system that is based on a balance of prevention, appraisal, and process verification activities. Another comment asks whether the industry should use industry standards and tests now used.

A few comments request that we clarify proposed § 111.35(h) to make it clear whether the section recommends or requires the use of available USP, AOAC International (formerly Association of Official Analytical Chemists) or FDA methods. One comment recommends that the final rule give companies flexibility to use the method(s) most suitable to the ingredient they are testing and the specification they have set. The comment adds that companies should then be required to ensure, through appropriate rationale and data, that the method is indeed suitable and produces accurate and reproducible results.

(Response) We agree that companies should have the flexibility to adopt the method most suitable to the ingredient they are testing. As discussed in the preamble to the proposal (68 FR 12157 at 12163 and 12208), official methods, such as AOAC International methods, are validated in collaborative studies using several laboratories under identical conditions and the AOAC International methods are often cited as ''official validated methods.'' Other method validations are conducted in a single laboratory by repeating the same test multiple times. In the case of methods used to support specific regulatory applications to FDA, data and information about methods that are developed and conducted in a single laboratory by repeating the test multiple times are sent to us, together with appropriate samples and reference materials so the test can be repeated in an agency laboratory. Typical validation characteristics include accuracy, precision, specificity, detection limit, quantitation limit, linearity, range, and robustness.

The process of method validation discussed in the previous paragraph is a formal process for demonstrating that procedures are suitable for their intended use. Although many methods that are scientifically valid have been formally validated, other methods may not have been subject to the formal validation process, e.g., by collaborative studies using multiple laboratories, but nonetheless remain scientifically valid because they are, in fact, suitable for their intended use. For this reason, we stated that the 2003 CGMP Proposal would permit tests using methods other than those that are officially validated (68 FR 12157 at 12163). Consistent with the view that we expressed in the 2003 CGMP Proposal, we believe a scientifically valid method is one that is accurate, precise, and specific for its intended purpose. In other words, a scientifically valid test is one that consistently does what it is intended to do.

Under final § 111.75(h)(1), you must ensure the tests and examinations you use to determine whether the specifications are met are appropriate, scientifically valid methods. Under final § 111.75(h)(2) the tests and examinations you use must include at least one of the following: (1) Gross organoleptic analysis, (2) macroscopic analysis, (3) microscopic analysis, (4) chemical analysis, or (5) other scientifically valid methods.

(Comment 193) One comment questions how a company would know of all the available scientifically valid methods when it deals with hundreds of items. The comment states it cannot be expected to have expertise in the assay methodology for so many different ingredients.

Several comments suggest we make fuller use of available monographs and other resources on test methods and method development. These sources include USP and AHP monographs, AOAC International, the European Pharmacopoeia, and the WHO. The comments urge us to disseminate information on these additional resources.

Many comments assert that several organizations have published relevant analytical methods, such as macroscopic, microscopic, and chemical methods, that can be used in identifying herbal ingredients. These comments suggest that we should acknowledge those methods and organizations as authoritative sources of quality standards.

(Response) In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12209), we acknowledged that validated methods exist in official compendia for vitamins, minerals, and several botanicals, and we recommended you use validated methods whenever such methods are available. We explicitly stated that you may use validated methods that can be found in official references, such as AOAC International, USP, and others.

As discussed in this section (see response to comment 196), we believe that it is sufficient to provide in this preamble general guidance on what we consider to be scientifically valid tests, such as those based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research, and leave it to the manufacturer to decide what scientifically valid tests or examinations to use in a given operation. In the future, we may consider issuing guidance as to sources of appropriate tests or examinations, along with other guidances that we may find useful that relate to certain dietary supplement CGMP.

(Comment 194) One comment states the act prohibits us from imposing testing requirements for which scientifically valid methods are not generally available, and other comments believe that not all components have scientifically valid identification tests. Given the substantial ongoing efforts towards method development, the

comments believe that the proposed requirements for testing would impose standards on many products and ingredients that cannot be met through current and generally available methods.

(Response) We disagree that the statute prohibits us from imposing testing requirements. Section 402(g)(2) of the act states that dietary supplement CGMP regulations ''may not impose standards for which there is no current and generally available analytical methodology.'' We are not imposing such standards. The manufacturer must establish specifications for its product and components, and we have provided flexibility for how the manufacturer can determine whether those specifications are met. The manufacturer can test, examine, rely on a certificate of analysis (other than to verify the identity of dietary ingredients), or, in the case of a specification that is exempted from periodic testing of a finished batch, rely on other information that ensures that such an exempted product specification is met.

(Comment 195) One comment requests clarification on the definition of ''examination'' and asks whether it includes monitoring of process parameters as established in the master manufacturing record. If so, the comment questions whether this practice would satisfy the requirement now in final § 111.75(h)(1).

(Response) Under final § 111.75(h), scientifically valid tests and examinations include techniques such as gross organoleptic analysis, macroscopic analysis, chemical analysis, and other scientifically valid methods. As discussed in the response to comment 169, monitoring in-process parameters could encompass tests such as measuring pH or viscosity. Such tests would fall under ''other scientifically valid methods.''

(Comment 196) One comment contends that botanical identification is largely ignored in the 2003 CGMP Proposal. The comment states that botanical identification forms the basic foundation for botanical authenticity and that manufacturers have a legal responsibility to ensure the authenticity of claimed ingredients. The comment recommends that specific requirements for authentication of botanical ingredients be included in the final rule.

One comment points out the difficulty in identifying and analyzing all naturally occurring ingredients in herbs and plants and suggests several alternatives to testing for all such ingredients. Another comment requests that an herbal product containing 20 percent or more ethanol have relaxed testing requirements due to the bacteriostata properties of ethanol. One comment lists some alternatives for testing naturally occurring ingredients.

One comment requests clarification on the testing requirements for bovine cartilage products. The comment states there is no published method for extracting chondroitin sulfate from bovine cartilage. As a result, the comment assumes that testing for chondroitin sulfate would not be required for these products.

(Response) We believe that it is sufficient to provide in this preamble general guidance about testing, such as our discussion that scientifically valid tests include official, validated methods as well as tests based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research. It is the manufacturer's responsibility to choose which scientifically valid tests or examinations to use in a given operation. Therefore, the final rule does not address the specific testing circumstances described in these comments, such as testing requirements for an herbal product that contains 20 percent or more ethanol, or for bovine cartilage products. The manufacturer is responsible for establishing specifications and meeting such specifications, consistent with the requirements in this final rule. In the future, we may consider issuing detailed guidance as to specific tests or examinations, along with other guidances that may be useful that relate to certain dietary supplement CGMP.

With respect to the comments that discuss botanical identification, we note that the 2003 CGMP Proposal referred to the draft report of the Dietary Supplement Working Group of FDA's Food Advisory Committee (68 FR 12157 at 12161) (Ref. 32). The draft report discusses the selection of the most appropriate and reliable identity test and the general principles for consideration in setting performance standards for such tests (Ref. 32). This report may provide useful guidance.

8. Final § 111.75(i)

Final § 111.75(i) requires you to establish corrective action plans for use when an established specification is not met. Final § 111.75(i) derives from proposed § 111.35(i)(1).

(Comment 197) One comment asks whether the proposed requirement to establish corrective action plans for use when an established specification is not met (proposed § 111.35(i)(1)) would apply to specifications for raw materials and finished goods as well as to in-process specifications.

(Response) The requirement to establish corrective action plans (final § 111.75(i)) applies to components, in-process specifications, and to the finished batch.

(Comment 198) One comment states that corrective action plans would be difficult to prepare for a variety of situations, such as for complex multivitamin and mineral formulas. One comment recommends this requirement be deleted. Another comment asserts that establishment of corrective action plans should be at the manufacturer's discretion.

(Response) We disagree that the final rule should not require you to establish corrective plans or that having such plans should be at the manufacturer's discretion. The purpose of having corrective action plans in place before a problem occurs is to help you to deal quickly and efficiently with problems as they arise.

You may have a corrective action plan to determine the steps to take if something goes wrong such as not meeting a specification. Moreover, a corrective action plan may include steps not only for dealing with an acute problem, but also for dealing with steps you would take to followup after the acute problem is resolved. For example, after you resolve an acute problem, such as a failure to meet an in-process specification, your corrective action plan may include testing of every finished batch, rather than a subset of finished batches, for some period of time to verify that the problem is resolved.

We acknowledge that it may not be practical to establish a corrective action plan for all circumstances, because not all circumstances are foreseeable. However, the comment asserting that it would be difficult to establish corrective action plans for the variety of situations that could come up for complex multivitamin and mineral formulas provided no basis for why manufacturers of such formulas could not anticipate specific situations that present potential problems.

(Comment 199) Some comments recommend that proposed § 111.35(i)(1) state ''Establish procedures,'' rather than ''Establish corrective action plans.''

(Response) The comments did not explain what, if any, practical difference would exist between ''procedures'' and ''corrective action plans.'' A corrective action plan is a procedure for which you must have a record in the master manufacturing record (final § 111.210(h)(5)). Because ''corrective action plans'' is a term that is commonly used in the industry, we have retained it in the final rule.

J. What Must You Do if Established Specifications Are Not Met? (Final § 111.77)

1. Final § 111.77

As we explain in section II of this document, we reorganized the final rule to make it more ''user-friendly'' and to clarify the rule's applicability to certain persons, items, or activities. Final § 111.77 is a new provision that clarifies your responsibilities and identifies those responsibilities in a more ''user-friendly'' fashion. We have identified in final § 111.77 the consequences of not meeting the specifications you establish under subpart E and when you can consider a treatment, in-process adjustment, or reprocessing to correct a failure to meet and established specification for a component, dietary supplement, packaging, or label. Subpart F does identify these consequences in several provisions which deal with the responsibility of quality control personnel to review and approve or reject components, dietary supplements, packaging, and labels. We determined it would add clarity to state the consequences for not meeting a specification in the same subpart in which the requirements to establish specifications are located.

2. Final § 111.77(a)

Final § 111.77(a) requires that for specifications established under § 111.70(a), (b)(2), (b)(3), (c), (d), (e), and (g) that you do not meet, quality control personnel, in accordance with the requirements in subpart F of this part, must reject the component, dietary supplement, package, or label unless it approves a treatment, an in-process adjustment, or reprocessing that will ensure the quality of the finished dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. No finished batch of dietary supplements may be released for distribution unless it complies with final § 111.123(b).

This provision identifies those specifications, if not fully met, that may be able to be corrected by treatment, in-process adjustment, or reprocessing and approved by quality control personnel. We emphasize, however, that even if, for example, corrections are approved, the finished batch of dietary supplement can not be released for distribution unless it is compliance with the requirements of final § 111.123(b) (discussed in section XI of this document).

Final § 111.77(a) derives from the following proposed provisions:

- Proposed § 111.50(d)(2), which would require the quality control unit not to approve and release for distribution any batch of dietary supplement that does not meet all specifications;
- Proposed § 111.50(f), which would require you to not reprocess a batch that deviates from the master manufacturing record unless approved by the quality control unit.
- Proposed § 111.50(g), which would require that a reprocessed batch of dietary supplement meet all specifications and that the quality control unit approve its release for distribution.
- Proposed § 111.35(i)(4)(i), which would require you, for any deviation or unanticipated occurrence which resulted in or could lead to adulteration of the component, dietary supplement, packaging, or label, to reject the component, dietary supplement, packaging, or label, unless the quality control unit determines that in-process adjustments are possible to correct the deviation or occurrence.
- Proposed § 111.35(i)(4)(ii), which would require you, for any deviation or unanticipated occurrence which resulted in or could lead to adulteration of the component, dietary supplement, packaging, or label, to not reprocess a rejected component or dietary supplement unless approved by the quality control unit.

3. Final § 111.77(b)

Final § 111.77(b) requires that for specifications established under final § 111.70(b)(1) that you do not meet, quality control personnel must reject the component and the component must not be used in manufacturing the dietary supplement. Final § 111.77(b) complements final § 111.70(b)(1) which requires you to establish an identity specification for components; final § 111.75(a)(1) which requires you to conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient; and final § 111.75(a)(2) which requires you to confirm the identity of all other components. As discussed earlier in this section, many comments recommended the final rule include a requirement for an identity test of incoming components to ensure quality and safety. We agree with these comments and earlier comments that point out it may not be possible to confirm the identity of some components after they have been processed into the finished batch of the dietary supplement. For these reasons, we have concluded that, if the component specification for identity is not met, you may not use the component in the manufacture of the dietary supplement. This component specification must be met and quality control personnel are restricted in what action must be taken if this specification is not met.

4. Final § 111.77(c)

Final § 111.77(c) requires that if you do not meet the specifications established under § 111.70(f), quality control personnel must reject the product and the product must not be packaged or labeled for distribution as a dietary supplement. As with final § 111.77(b), final § 111.77(c) limits the actions you can take to package and label product you receive for packaging and labeling from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier). Final § 111.77(c) complements final § 111.70(f), which requires you to establish a specification for such received product and final § 111.75(e), which requires you to visually examine the product, before you package or label it, and have documentation to determine whether the specifications that you established under § 111.70(f) are met. If you do not meet the specifications under final § 111.70(f), you must reject the product and not package or label the product for distribution as a dietary supplement.

K. Comments on Shelf Life

In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12203), we stated that we had considered whether to propose requirements for expiration dating, shelf life dating, or ''best if used by'' dating (referred to in this preamble as shelf life or expiration dating). We recognized that there are current and generally available methods to determine the expiration date of some dietary ingredients, such as vitamin C. However, we were uncertain whether there are current and generally available methods to determine the expiration dating of other dietary ingredients, especially botanical dietary ingredients. We did not propose to require expiration dating because we had insufficient scientific information to determine the biological activity of certain dietary ingredients used in dietary supplements, and such information would be necessary to determine an expiration date. Further, because official validated testing methods (e.g., AOAC International or FDA) for dietary supplements are evolving, especially for botanical dietary ingredients, such methods are not always available to assess the strength of

a dietary ingredient in a dietary supplement.

The preamble to the 2003 CGMP Proposal emphasized that, if you use an expiration date on a product, you should have data to support that date (68 FR 12157 at 12204). We recommended that you have a written testing program designed to assess the stability characteristics of the dietary supplement, and that you use the results of the stability testing to determine appropriate storage conditions and expiration dates.

In the 2003 CGMP Proposal (68 FR 12157 at 12204), we invited comment on whether any final rule should contain provisions regarding expiration dating and the feasibility of conducting tests needed to support such dates. We also invited comment on whether to require expiration dating on certain dietary ingredients and not others, for example, require expiration dating of vitamin, mineral, and amino acid, but not of botanical dietary ingredients.

(Comment 200) Several comments agree with our decision not to require expiration dating on labels for dietary supplements at this time, because of the wide range of products and the need for additional data. Most of these comments state, however, that manufacturers should be allowed to include a ''best if used by'' date. One comment suggests addressing the issue in a separate rulemaking. Other comments support an expiration date because consumers and retailers expect one, and some markets require one. Some comments state that the expiration date or statement of product shelf life will help ensure that the product meets its label claims and potency.

Many comments state an expiration date on a label must be supported by a rationale or data on stability testing. Some of those comments suggest that manufacturers should have flexibility in the type of supporting data used. Although label claims should be confirmed by shelf life testing when analytical methods exist, data could come from a manufacturer's experience with the product or accelerated stability testing on similar products with the same storage container. One comment points out that some manufacturers already use stability testing. Another comment recommends that we provide a guidance document on supporting data.

One comment suggests stringent supporting data are not needed for a ''best if used by'' date, because that date provides a recommended time frame to ensure the best quality. Another comment asserts that the discussion about expiration dates in the 2003 CGMP Proposal gives the impression that the required level of supporting data is similar to the requirements for drug labeling, rather than the requirements for food shelf life labeling. Another comment recommends that a general maximum shelf life of 4 or 5 years should be included in the rule, with shortened or lengthened shelf lives for individual products as data become available.

(Response) These comments do not provide data or information that would reduce the uncertainty about the feasibility of conducting tests to support an expiration date and, thus, do not persuade us to alter our position not to require that you establish an expiration date for your product. Indeed, the comments generally concur with that position. Because the final rule does not require that you establish an expiration date, we decline to offer guidance on the type of data that are acceptable to support an expiration date, other than to repeat that any expiration date that you place on a product label (including a ''best if used by'' date) should be supported by data.

L. What Representative Samples Must You Collect? (Final § 111.80)

Final § 111.80 sets forth requirements to collect representative samples of components, packaging, and labels (final § 111.80(a)); in-process materials (final § 111.80(b)); the finished batch of dietary supplement (final § 111.80(c)); product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) (final § 111.80(d)); and packaged and labeled dietary supplements (final § 111.80(e)). Final § 111.80(a) through (e) derive from proposed § 111.37(b)(11)(i) through (b)(11)(iv).

1. Final § 111.80(a)

Final § 111.80(a) requires you to collect representative samples of each unique lot of components, packaging, and labels that you use to determine whether the components, packaging, and labels meet specifications established in accordance with § 111.70(b) and (d), and as applicable, final § 111.70(a) (and, when you receive components, packaging, or labels from a supplier, representative samples of each unique shipment, and of each unique lot within each unique shipment). Final § 111.80(a) derives from proposed § 111.37(b)(11)(i). Final § 111.80(a) includes changes related to our review of the proposed requirements for clarity. We had used the term ''shipment lot'' in several proposed requirements, including § 111.35(g)(1)(i) (requirement to test components that you receive), § 111.37(b)(11)(i) (requirement to collect representative samples of components that you receive), § 111.40(a)(4) (requirements for components that you receive), § 111.40(b)(5) (requirements for packaging and labels that you receive), and § 111.50(c)(5) (requirement to identify materials that you use in the batch production record). Some of these proposed requirements (e.g., those in §§ 111.40(a)(4) and (b)(3) and 111.50(b)(5)) make clear that you must be able to trace each lot of materials you receive to each separate shipment that contains that lot. To clarify and emphasize this meaning of shipment lot, we are revising proposed § 111.37(b)(11)(i) so that the representative samples you collect must come from ''each unique shipment, and of each unique lot within each unique shipment.'' We make analogous revisions throughout the final rule as necessary.

As discussed in this section, final § 111.70(b) sets forth the requirements to establish specifications for components, final § 111.73 requires you to determine if the specifications established are met, and final § 111.75(a) sets forth the criteria you use to determine whether these specifications are met. Likewise, final § 111.70(f) sets forth the requirements to establish specifications for product that you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), final § 111.73 requires you to determine if specifications established are met, and final § 111.75(e) sets forth the criteria to use to determine whether these specifications are met.

For consistency with the regulations in final §§ 111.70 and 111.75, we are separating the requirement to collect representative samples of components (final § 111.80(a)) from the requirement to collect representative samples of product that you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) (final § 111.(80)(d)).

We did not receive comments specific to proposed § 111.37(b).

2. Final 111.80(b)

Final § 111.80(b) requires you to collect representative samples of in-process materials for each manufactured batch at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record, where control is necessary to ensure the identity, purity, strength, and composition of dietary supplements, to

determine whether the materials meet specifications established under final § 111.70(c), and, as applicable, final § 111.70(a). Final § 111.80(b) derives from proposed § 111.37(b)(11)(ii).

We did not receive comments specific to proposed § 111.37(b)(11)(ii).

3. Final 111.80(c)

Final § 111.80(c) requires you to collect representative samples of a subset of finished batches of each dietary supplement you manufacture, which you identify through a sound statistical sampling plan (or otherwise every finished batch), before releasing for distribution, to verify that the finished batch of dietary supplement meets product specifications established in accordance with final § 111.70(e), and, as applicable, final § 111.70(a). Final § 111.80(c) derives from proposed § 111.37(b)(11)(iii). Final § 111.80(c) includes changes associated with final § 111.75(c) which provides flexibility for you to test or examine a subset of finished batches you select through a sound statistical sampling plan rather than to test or examine all finished batches. Under final § 111.75(c) the tests or examinations you conduct at the finished batch stage verify that your process is in control.

We did not receive comments specific to proposed § 111.37(b)(11)(iii).

4. Final § 111.80(d)

Final § 111.80(d) requires you to collect representative samples of each unique shipment, and of each unique lot within each unique shipment, of product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) to determine whether the received product meets the specifications established under final § 111.70(f), and, as applicable, final § 111.70(a). Final § 111.80(d) derives from proposed § 111.37(b)(11)(i). We did not receive comments specific to this proposed requirement. However, we are making changes to final § 111.80(d) consistent with those described for final § 111.80(a).

5. Final § 111.80(e)

Final § 111.80(e) requires you to collect representative samples of each lot of packaged and labeled dietary supplements to determine whether the packaging and labeling of the packaged and labeled dietary supplements meet specifications established in accordance with final §111.70(g), and, as applicable, final § 111.70(a). Final § 111.80(e) derives from proposed § 111.37(b)(11)(iv). Final § 111.80(e) includes revisions associated with final § 111.70(g), which requires you to establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements. Final § 111.70(g) includes specifications that determine whether you used the packaging specified in the master manufacturing record and you applied the label specified in the master manufacturing record. Under final § 111.70(a) and (g) the parameters that we proposed to specify under proposed § 111.37(b)(11)(iv) are the required specifications for packaged and labeled dietary supplements.

Final § 111.80(e) includes a change to clarify the exact specifications by citing the relevant sections. Final § 111.80(e) also includes an editorial change in that you are required to ''determine whether'' specifications are met rather than to ''determine that'' specifications are met. We are making this change because ''determine that specifications are met'' may be interpreted as a predetermined outcome, i.e., that specifications will, in fact, be met.

We did not receive comments specific to proposed § 111.37(b)(11)(iv).

M. What Are the Requirements for Reserve Samples? (Final § 111.83)

Final § 111.83 sets forth requirements to collect and hold reserve samples of dietary supplements. Final § 111.83 derives from proposed §§ 111.37(b)(12), 111.50, and 111.83(b)(2).

Under proposed § 111.37(b)(12) we would require holding reserve samples as an operation performed by the quality control unit. Under proposed § 111.50(h), we proposed that you collect representative reserve samples of each batch of dietary supplement. Consistent with the changes that we are making to final § 111.80, final § 111.83 does not specify who must collect and hold the required reserve samples. However, under final § 111.105(g), quality control personnel retain oversight of the collection and holding of the required reserve samples. Because the requirement to collect and hold reserve samples is not an operation that must be performed by quality control personnel, we are including the requirement to collect reserve samples in subpart E as part of the elements of a production and process control system rather than in subpart F as part of the requirements for quality control personnel.

For consistency with terms used elsewhere in the final rule, final § 111.83 requires that you ''hold'' reserve samples rather than ''keep'' them.

1. Final § 111.83(a)

Final § 111.83(a) requires you to collect and hold reserve samples of each lot of packaged and labeled dietary supplements that you distribute. Final § 111.83(a) derives, in part, from proposed § 111.37(b)(12), which would require the quality control unit to keep the reserve samples and, in part, from proposed § 111.50(h), which would require you to collect representative reserve samples from each batch of dietary supplement.

(Comment 201) Several comments ask for clarification of the requirements for representative and reserve samples as proposed in § 111.37(b)(11) and (b)(12). One comment notes that proposed § 111.37(b)(11) does not indicate whether representative samples are also collected to serve as the reserve samples described in proposed § 111.37(b)(12) and asks whether the items in proposed § 111.37(b)(11)(i) through (b)(11)(iv) are to be kept as reserve samples.

(Response) As discussed in section VI of this document, we are adding a definition of ''reserve sample'' to reduce the potential for confusion between requirements for reserve samples and requirements for representative samples. A reserve sample is a representative sample that is held for a designated period of time.

2. Final § 111.83(b)(1)

Final § 111.83(b)(1) requires the reserve samples to be held using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which it is distributed for packaging and labeling elsewhere. Final § 111.83(b)(1) derives from proposed § 111.83(b)(2) which we proposed to include with the requirements for holding and distributing. The final sections that derive from proposed § 111.83(b)(2) are in subpart M (final § 111.465). However, we are duplicating these requirements in final § 111.83(b)(1) for clarity and ease of use, so that you have information about the requirements for the container-closure system for holding reserve samples of packaged and labeled dietary supplements in the same section as the requirements to collect the samples.

3. Final § 111.83(b)(2)

Final § 111.83(b)(2) requires that reserve samples be identified with the batch, lot, or control number. Final

§ 111.83(b)(2) derives from proposed § 111.37(b)(12)(i) with editorial changes associated with the reorganization. We have added ''control number'' to the provision for consistency with other provisions of the final rule which refer to a ''control number'' in addition to a ''batch or lot number.''

We did not receive comments specific to proposed § 111.37(b)(12)(i).

4. Final § 111.83(b)(3)

Final § 111.83(b)(3) requires that reserve samples be retained for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with those reserve samples, for use in appropriate investigations. Final § 111.83(b)(3) derives from proposed § 111.37(b)(12) which would require the quality control unit to keep the reserve samples for 3 years from the date of manufacture for use in appropriate investigations including, but not limited to, consumer complaint investigations to determine, for example, whether the dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition, as well as from proposed § 111.50(h) which would require reserve samples to be kept for 3 years from the date of manufacture. We discuss the change from 3 years to 2 years and the change from ''date of manufacture'' to ''the date of distribution'' in connection with the recordkeeping requirements in subpart P, in section XXI of this document.

Final § 111.83(b)(3) thus provides flexibility in determining how long you must hold reserve samples of packaged and labeled dietary supplements.

Final § 111.83(b)(3) does not include the proposed examples of investigations that may require the use of reserve samples because these examples are not requirements.

(Comment 202) Many comments address the requirement to keep the reserve samples after manufacture and recommend that expiration dates be a factor when determining the amount of time reserve samples should be kept and maintained. Most of the comments recommend holding reserve samples of packaged and labeled dietary supplements for 3 years from the date of manufacture or, when an expiration date has been established by the manufacturer, for 1 year after the expiration date. Other comments recommend holding reserve samples for time periods ranging from 6 months to 2 years after the expiration date.

(Response) The final rule contains requirements similar to the suggestions made by the comments. The final rule provides flexibility to hold reserve samples for 1 year past the shelf life date, when such dating is used. Any shelf life date that you include on the label of the product should be supported by data.

5. Final § 111.83(b)(4)

Final § 111.83(b)(4) requires that reserve samples consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the dietary supplement meets product specifications. Final § 111.83(b)(4) derives from proposed § 111.37(b)(12)(ii) which would require that the reserve samples consist of at least twice the quantity necessary for tests.

Final § 111.83(b)(4) provides that the reserve samples may be used for examinations or tests and to determine whether or not the dietary supplement meets product specifications, as a revision associated with final § 111.75.

(Comment 203) One comment agrees that twice the quantity necessary for testing should be collected and held.

(Response) The final rule is consistent with this comment.

N. Who Conducts a Material Review and Makes a Disposition Decision? (Final § 111.87)

Final § 111.87 requires quality control personnel to conduct all required material reviews and make all required disposition decisions. Final § 111.87 derives from a number of proposed requirements for conducting a material review and making a disposition (§§ 111.35(i) and (n), 111.37(b)(5) and (b)(14), 111.40(a)(3), 111.50(d)(1), and 111.85(a) and (c)). Under each of these provisions, the quality control unit would have an oversight role and would review and approve all material reviews and all disposition decisions. Under some of these provisions (i.e., §§ 111.50(d)(1) and 111.85(a) and 85(c)) the quality control unit would conduct the material review itself and make the disposition decision.

(Comment 204) One comment disagrees that the quality control unit must conduct the material review and make the disposition decision. The comment argues that manufacturing personnel are better qualified to conduct the review and make disposition decisions because they are often engineers and have the relevant expertise regarding the use of machinery and people to produce a product. In contrast, the comment asserts that quality control unit personnel generally are chemists with expertise only in testing and little expertise in manufacturing. The comment asserts that the quality control unit should not be expected to make decisions concerning manufacturing operations; however, it should be informed of changes so it can evaluate the results of reprocessing on the finished product.

(Response) We agree, in part, with the comments and the final rule simplifies the provisions regarding a material review and disposition decision. Quality control personnel can conduct the material review and disposition decision by reviewing the underlying information gathered or obtained by other qualified personnel and then making the final decision. Under the final rule, we retain the principle that qualified individuals other than quality control personnel can contribute to the quality control personnel's material review and disposition decision. The final rule sets forth the following requirements:

- Under final § 111.87, quality control personnel must conduct all required material reviews and make all required disposition decisions;
- Under final § 111.103, you must establish and follow written procedures for conducting a material review and making a disposition decision; and
- Under final § 111.140(b)(3)(vii), documentation of a material review and disposition decision and followup must include the signature of the individual(s) designated to perform the quality control operations, who conducted the material review and made the disposition decision, and of any qualified individual who provided information relevant to that material review and disposition decision.

Taken in total, the final rule establishes a system in which you have flexibility to develop procedures that suit your organization, including having qualified individuals, other than the designated quality control personnel, provide information relevant to the material review and disposition decision. For example, under final § 111.140(b)(3), you could have a qualified individual in the production department prepare a report that includes all the required documentation and information and provide a signed copy of that report to designated quality control personnel. An individual designated to perform quality control operations would then read that report, add to it if necessary, conduct any additional investigations if necessary, and if he or she agrees with the report, co-sign the report or an amended report that includes additional documentation or information, thus completing a material review and disposition decision.

The final rule provides for the participation of qualified individuals, other than those designated to perform quality control operations, in conducting the material review. In addition, as already discussed, under final § 111.12(b) you may assign a qualified individual who has responsibilities for operations other than quality control to perform quality control operations, provided that the individual has distinct and separate responsibilities related to performing quality control operations.

O. What Requirements Apply to Treatments, In-Process Adjustments, and Reprocessing When There is a Deviation or Unanticipated Occurrence or When a Specification Established in Accordance with § 111.70 Is Not Met? (Final § 111.90)

1. Final § 111.90

Final § 111.90 is a unified provision that clarifies your responsibilities regarding treatment or in-process adjustments to a component, and in-process adjustments or reprocessing of a dietary supplement, in a more ''user-friendly'' fashion. We have identified in one provision the restrictions that apply to these operations. Final § 111.90 derives from proposed §§ 111.35(i)(4)(i), (i)(4)(ii), and (i)(4)(iii); 111.50(d)(1), (f), and (g); and 111.65(d).

Final § 111.90 includes the following changes we are making to the proposed provisions for consistency and clarity:

- We are making revisions to make the section consistent with the definition of ''reprocessing'' in final § 111.3, which refers only to ''components or dietary supplements that have been previously removed from manufacturing.''
- We are adding ''treatments'' as a step that quality control personnel could approve, because that term better describes actions that could be taken to correct a deviation or unanticipated occurrence with a component, packaging, or label.
- We are clarifying that it is quality control personnel who reject components, packaging, or labels.
- We are clarifying that quality control personnel approve the treatment, in-process adjustment, or reprocessing rather than determine whether the treatment, in-process adjustment, or reprocessing is possible.
- We are clarifying that, with respect to labels, the provision applies to the potential that a label not specified in the master manufacturing record could be used.
- We are making changes to be consistent with the new provision, final § 111.77.

(Comment 205) One comment recommends deletion of proposed § 111.35(i)(4) and (i)(4)(i), arguing that the principles of those sections are covered under proposed § 111.35(i)(2) and (i)(3).

(Response) We disagree with the comment's assertion. The requirements of proposed § 111.35(i)(4) and (i)(4)(i) are not covered by proposed § 111.35(i)(2) and (i)(3). All the sections are related, but deal with different aspects of corrective action. Proposed § 111.35(i)(2) and (i)(3) would require the firm to conduct a material review and make a disposition decision, while proposed § 111.35(i)(4) would prohibit the use of rejected ingredients unless the quality control unit determines that in-process adjustments are possible to correct the deviations or occurrence. We are making no changes as suggested by this comment and the primary elements of proposed § 111.35(i)(4) are retained in final § 111.90.

(Comment 206) A few comments state their support for the requirement that the quality control unit have the authority to determine whether adjustments are possible to correct a deviation.

(Response) We are retaining the proposed requirement for quality control personnel in final § 111.90.

2. Final § 111.90(a)

Final § 111.90(a) requires that you must not reprocess a rejected dietary supplement or treat or provide an in-process adjustment to a component, packaging, or label to make it suitable for use in the manufacture of a dietary supplement, unless: (1) Quality control personnel conduct a material review and make a disposition decision to approve the reprocessing, treatment, or in-process adjustment and (2) the reprocessing, treatment, or in-process adjustment is permitted by § 111.77.

Final § 111.90(a) derives from proposed §§ 111.35(i)(4)(ii) and 111.50(d)(1). We revised this provision to be consistent with the changes in final § 111.77.

(Comment 207) Several comments state their support for proposed § 111.35(i)(4)(ii), which would require the quality control unit to approve the reprocessing of any rejected component, dietary ingredient, or dietary supplement. However, not all comments agree that the quality control unit should have to conduct (under proposed § 111.50(d)(1)), rather than review and approve, a material review and disposition decision.

(Response) As discussed in this section, by ''conduct a material review and make a disposition decision,'' we do not intend to limit those who may participate in a material review and disposition decision to only those persons acting in their capacity as designated quality control personnel. Others may assist quality control personnel in gathering and considering information relevant to the review and decision, however the quality control personnel have the responsibility to conduct a material review and make disposition decisions. Thus, we are retaining in final § 111.90(a) the requirements in proposed §§ 111.25(i)(4)(ii) and 111.50(d)(1).

3. Final § 111.90(b)

Final § 111.90(b) requires that you must not reprocess any dietary supplement or treat or provide an in-process adjustment to a component to make it suitable for use in the manufacture of a dietary supplement, unless: (1) Quality control personnel conduct a material review and make a disposition decision based on a scientifically valid reason and approve the reprocessing, treatment, or in-process adjustment and (2) the reprocessing, treatment or in-process adjustment is permitted by § 111.77. Final § 111.90(b) derives from proposed §§ 111.35(i)(4)(iii), 111.50(f), and 111.65(d). We revised this provision to be consistent with the changes in final § 111.77.

(Comment 208) As discussed in section VI of this document (discussion of the definition of ''reprocessing''), some comments object to the restrictions in the definition of reprocessing in proposed § 111.3 because the definition would not permit the reprocessing of ingredients that may have been removed because of insanitary conditions even if there are processes available that are safe and effective in removing foreign matter, microorganisms, or chemicals that may have rendered the ingredient ''insanitary.'' These comments also object to proposed § 111.35(i)(4)(iii) for the same reasons. A few comments argue that a manufacturer should be able to reprocess a component or dietary supplement if it has been rejected because of contamination with microorganisms or types of contamination, such as heavy metals, if the quality control unit approves the reprocessing. These comments indicate this is the industry practice, one based on a scientific rationale for doing the reprocessing and that ensures other quality attributes of the product are not affected.

Some comments state that the requirement is more strict than the food or drug CGMP requirements, noting that

reprocessing is widely accepted and allowed in the food CGMPs. Other comments believe that the prohibition in proposed § 111.35(i)(4)(iii) against reprocessing materials contaminated with microorganisms should be limited to materials contaminated with health-hazardous microorganisms.

(Response) As we discussed in the response to comment 53 for the definition of ''reprocessing,'' we agree with the comments that state that in-process materials can be reprocessed when there are suitable processes available. However, as noted by the comments, it is critical that there be appropriate oversight of the reprocessing so the quality of the dietary supplement is not compromised. Final § 111.90(b) provides for the flexibility requested by the comments, provided that there is oversight by quality control personnel.

(Comment 209) Proposed § 111.35(i)(4)(iii) mentions ''microorganism or other contaminants, such as heavy metals.'' One comment proposes that other contaminants, such as pesticides and aflatoxin, should be mentioned. Another comment suggests that the final rule should specify limits for heavy metals in dietary supplements.

(Response) We decline to revise the final rule as suggested by the comments. It is impractical to provide an exhaustive list of relevant types of contamination, and a list that is longer, but not exhaustive, is more likely to be misunderstood as suggesting that the only types of contamination that are significant are the types of contamination in the list. For that reason, we have eliminated the reference to contamination to clarify that in any instance where it is appropriate quality control personnel must ensure that the disposition decision is based on a scientifically valid reason and also approve the reprocessing.

(Comment 210) One comment notes that in the May 9, 2003, satellite broadcast concerning the 2003 CGMP Proposal, we indicated that treating a component or dietary supplement with irradiation as a means to reduce or eliminate the microbial load was acceptable as long as the treatment was part of the process for producing that material. The comment asks for confirmation that irradiation of components or dietary supplements is allowed under part 179 (21 CFR part 179), even though such treatments are not listed in the table provided in § 179.26(b).

(Response) We are unable to provide the requested confirmation. Under section 201(s) of the act, irradiation intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food is a food additive that requires premarket review and approval before it can be used in food. Our Office of Food Additive Safety is currently reviewing a food additive petition for the use of irradiation on dietary ingredients and dietary supplements. Until that review process is completed and we have authorized this use of irradiation through a final rule codified in part 179, irradiation of dietary ingredients and dietary supplements as a means to reduce or eliminate microbial loads is not permitted. However, you may use an irradiated component (such as a spice that is used to flavor a dietary supplement) when the irradiation of that component is allowed under § 179.26.

4. Final § 111.90(c)

Final § 111.90(c) requires that any batch of dietary supplement that is reprocessed, that contains components that you have treated, or to which you have made in-process adjustments to make them suitable for use in the manufacture of the dietary supplement must be approved by quality control personnel and comply with final § 111.123(b) before releasing for distribution. Final § 111.90(c) derives from proposed § 111.50(g).

Final § 111.90(c) also includes conforming revisions to clarify that a dietary supplement that contains a component treated before use or adjusted in-process, or that has had in-process adjustments to make it suitable for use in the manufacture of a dietary supplement, must be approved by quality control personnel and comply with final § 111.123(b) before releasing for distribution. We revised this provision to be consistent with the changes in final §§ 111.77 and 111.123(b).

Final § 111.90(c) also includes revisions to reflect the final provisions that relate to reprocessing and in-process adjustments (see final §§ 111.113, 111.120, and 111.155).

(Comment 211) One comment asserts that a reprocessed product should be retested to confirm that it meets product specifications.

(Response) Under final § 111.75(c) and (d) quality control personnel have flexibility to determine whether tests or examinations are necessary to ensure that a reprocessed product meets product specifications.

P. Under This Subpart, What Records Must You Make and Keep? (Final § 111.95)

1. Final § 111.95(a)

Final § 111.95(a) requires you to make and keep records required under this subpart in accordance with subpart P. Final § 111.95(a) derives from proposed § 111.35(o). Some of the records required under subpart E are set forth as recordkeeping requirements in other subparts of this final rule, such as those related to receiving records for components, packaging, and labels in subpart G, and the results of testing or examination in subpart J. The record requirements not specifically required in other related subparts are listed in subpart E.

(Comment 212) One comment supports the recordkeeping requirements, states that the records provide a valuable paper trail that will allow manufacturers to identify and fix problems in the process, and suggests the requirements protect consumers from adulterated and misbranded products.

(Response) We agree. Under final § 111.95(a), a firm must make and keep records required by subpart E in accordance with subpart P. As discussed in this section, firms are required to keep the records necessary for determining whether their products are made in accordance with specifications. This will help them identify and correct any problems. In addition, under subpart P, the records must be kept for 1 year past the shelf life date (if shelf life dating is used) or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records. Moreover, firms must make their records available to us for inspection and copying, which will permit us to determine whether firms are manufacturing, packaging, labeling, and holding dietary supplements in accordance with the requirements of this rule.

2. Final § 111.95(b)

Final § 111.95(b) specifies the records you must make and keep under subpart E. Under the reorganization several recordkeeping requirements of proposed § 111.35 are set forth in other subparts.

Final § 111.95(b)(1) requires you to make and keep records of the specifications established. Final § 111.95(b)(1) derives from proposed § 111.35(o)(1).

Final § 111.95(b)(2) requires you to make and keep records of your qualification of a supplier for the purpose of relying on the supplier's

certificate of analysis. Final § 111.95(b)(2) is a record that is required under final § 111.75(a)(2)(B).

Final § 111.95(b)(3) requires you to make and keep documentation for why meeting in-process specifications, in combination with meeting component specifications, helps ensure that the dietary supplement meets the specifications for identity, purity, strength, and composition and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement. Final § 111.95(b)(3) refers to records required under final § 111.70(c)(2).

Final § 111.95(b)(4) requires you to make and keep documentation for why the results of appropriate tests or examinations for the product specifications selected under final § 111.75(c)(1) ensures that the dietary supplement meets all product specifications. Final § 111.95(b)(4) is a record that is required under final § 111.75(c)(3).

Final § 111.95(b)(5) requires you to make and keep documentation for why any component and in-process testing, examination, or monitoring, and any other information, will ensure that a product specification that is exempted under final § 111.75(d) is met without verification through periodic testing of the finished batch, including documentation that the selected specifications tested or examined under final § 111.75(c)(1) are not able to verify that the production and process control system is producing a dietary supplement that meets the exempted product specification and there is no scientifically valid method for testing or examining such exempted product specification at the finished batch stage. Final § 111.95(b)(5) refers to a record required under final § 111.75(d)(1). As previously discussed in this section, we are issuing an interim final rule, published elsewhere in this issue of the **Federal Register**, that sets forth a procedure for requesting an exemption from the requirement that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. Included in the interim final rule is an amendment to final § 111.95(b) adding a new paragraph (b)(6) requiring the retention of FDA's response to a petition submitted under § 111.75(a)(1)(ii) that provides for an exemption from the provision of § 111.75(a)(1)(i).

(Comment 213) One comment recommends the recordkeeping requirements of proposed § 111.35(m) be moved to follow the requirements for appropriate test methods because these requirements are related and probably best understood without intervening information.

(Response) Consistent with this comment, the recordkeeping requirements of proposed § 111.35(m) are set forth in final subpart J instead of subpart E.

XI. Comments on Requirements for Quality Control (Final Subpart F)

A. Organization of Final Subpart F

Proposed § 111.37 set forth requirements for quality control operations. Other proposed requirements related to quality control operations were set forth in other sections. For example, proposed § 111.40(a) would require the quality control unit to perform operations associated with components that you use in the manufacturing process. Proposed § 111.45 would establish requirements for the master manufacturing record and would have the quality control unit review and approve each master manufacturing record. Proposed § 111.50 would have the quality control unit review batch production records.

As shown in table 7 of this document, the final rule reorganizes the requirements related to quality control operations into a distinct subpart (final Subpart F—Production and Process Control System: Requirements for Quality Control Operations). Table 7 lists the sections in final subpart F and identifies the proposed sections that form the basis for the sections in the final rule.

TABLE 7.—DERIVATION OF SECTIONS IN FINAL SUBPART F

Final Rule	2003 CGMP Proposal
§ 111.103 What are the requirements under this subpart F for written procedures?	N/A
§ 111.105 What must quality control personnel do?	§ 111.37(a), (b)(1), (b)(11), and (b)(12)
§ 111.110 What quality control operations are required for laboratory operations associated with the production and process control system?	§ 111.37(b)(9) and (b)(13)
§ 111.113 What quality control operations are required for a material review and disposition decision?	§ 111.35(i)(2), (i)(3), (i)(4)(i), (i)(4)(ii), (j), and (n) § 111.37(b)(3) § 111.37(c) § 111.40(a)(3) and (b)(2) § 111.50(d)(1) § 111.65(d) § 111.70(c)
§ 111.117 What quality control operations are required for equipment, instruments, and controls?	§ 111.30(b)(4), (b)(6), (b)(7), and (b)(8)
§ 111.120 What quality control operations are required for components, packaging, and labels before use in the manufacture of a dietary supplement?	§ 111.35(i)(4)(i) and (i)(4)(ii) § 111.37(b)(2) and (b)(10) § 111.40(a)(3) and (b)(2) § 111.50(e)(1)
§ 111.123 What quality control operations are required for the master manufacturing record, the batch production record, and manufacturing operations?	§ 111.35(e)(2), (f), (i)(2), and (o)(2) § 111.37(b)(2), (b)(4), (b)(5), and (b)(11)(iii) § 111.45(c) § 111.50(d)(1) and (d)(2) § 111.50(g)
§ 111.127 What quality control operations are required for packaging and labeling operations?	§ 111.37(b)(2) and (b)(10) § 111.40(a)(2) and (a)(3) § 111.70(c), (d), and (e)
§ 111.130 What quality control operations are required for returned dietary supplements?	§ 111.37(b)(2) and (b)(15) § 111.85(a)
§ 111.135 What quality control operations are required for product complaints?	§ 111.95
§ 111.140 Under this subpart F, what records must you make and keep?	§ 111.35(j) § 111.37(c) and (d)

B. Highlights of Changes to the Proposed Requirements for Quality Control Operations

1. Revisions

The final rule:

- Reflects that the rule applies to persons who manufacture, package, label, or hold dietary supplements

unless subject to an exclusion under § 111.1;

- Changes the requirement for a quality control unit to a requirement for quality control operations performed by quality control personnel;
- Requires quality control personnel to review and approve documentation for why meeting in-process specifications will ensure the specifications for identity, purity, strength, and composition of a dietary supplement are met;
- Requires quality control personnel to review and approve documentation setting forth the basis for qualifying a supplier of a component;
- Requires quality control personnel to review and approve documentation of your basis for why meeting certain selected specifications in a subset of finished batches will ensure your finished batch of the dietary supplement meets all product specifications for identity, purity, strength, and composition and limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the dietary supplement; and
- Requires quality control personnel to review and approve documentation for why a product specification exempted from the verification requirements in final subpart E is met without verification through periodic testing of the finished batch.

2. Changes Associated With the Reorganization

The final rule:

- Reduces redundant provisions and
- Combines parts of various proposed requirements that were scattered throughout the 2003 CGMP Proposal.

3. Changes After Considering Comments

The final rule:

- Incorporates a new requirement to establish, and keep as a record, written procedures for quality control operations;
- Simplifies the requirements associated with conducting a material review and making a disposition decision;
- Requires quality control personnel to ensure that representative samples are collected rather than collecting these samples;
- Requires quality control personnel to ensure that reserve samples are held rather than quality control personnel holding these samples;
- Requires quality control personnel to ensure tests or examinations are appropriate rather than conduct these tests or examinations; and
- Requires review by quality control personnel of all records for calibration of instruments, and for calibrations, inspections, and checks of automatic, mechanical, or electronic equipment to be performed on a periodic basis rather than at the time the record is made.

C. General Comments on Proposed § 111.37 (Final Subpart F)

(Comment 214) Some comments support the use of a quality control unit and recognize it as an important need in manufacturing operations. Some comments assert the quality control unit may not have all the responsibilities listed in proposed § 111.37 because there may be some duties contracted out to someone else, such as testing that could be sent to a contract laboratory, or some duties that may be better suited for employees in other organizational units. As an example, a few comments note that the instrument and equipment calibration functions in proposed § 111.37 may be better performed by individuals responsible for the equipment in their particular operational area, by those in a unit dedicated to equipment maintenance and calibration, or possibly by a third party, who is qualified by training and/or experience, to do these functions. Similarly, other comments note that other groups with the appropriate expertise may be assigned or required to review and approve proposed changes or procedures in manufacturing operations or to conduct material reviews and make disposition decisions. These comments assert the quality control unit should have overall responsibility and oversight for quality control functions but also should be able to rely on the expertise of other persons in the organization to accomplish the tasks.

(Response) As already discussed with respect to the definition of quality control personnel in section VI of this document, these comments may have misunderstood the quality control unit's role under the proposed rule. Consequently, we have added final § 111.12(b) in subpart B, discussed in section VII of this document, to state you must identify who is responsible for your quality control operations. Each person who is designated to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations.

The final rule requires quality control personnel to ensure all appropriate tests and examinations are conducted, and review and approve the results of all tests and examinations, but does not require that quality control personnel conduct the tests or examinations. Thus, you would not need to consider that an individual who conducts tests or examinations at a laboratory under contract to your organization is performing a quality control operation that must be performed by quality control personnel. However, you may choose to designate that individual as part of your quality control personnel and require that the tests or examinations conducted by that individual be quality control operations. Importantly, however, for the purposes of this final rule, we consider that a quality control operation performed by an individual under contract to you or by another third party is no different than a quality control operation performed by your employees who are designated to perform such operation. If, during the course of an inspection, we find the requirements of this final rule were not followed, we will hold you, rather than the contractor or other third party, responsible. The applicability of this final rule to contractors is discussed in detail in section VI of this document.

(Comment 215) Several comments request that the quality control unit focus on reviewing tasks performed by others rather than on performing the tasks itself.

(Response) We agree with these comments and have revised several provisions accordingly. For example, in the 2003 CGMP Proposal we would require the quality control unit to perform appropriate tests and examinations of incoming materials, in-process materials, each finished batch of dietary supplements, and each batch of packaged and labeled dietary supplements (proposed § 111.37(b)(13)). Under the final rule, quality control operations include ensuring appropriate tests and examinations are conducted (final § 111.110(b)) but do not include conducting these tests and examinations.

(Comment 216) One comment asks whether we expect the quality control unit to approve operational activities as soon as they occur or collectively at the end of the process. This and other comments argue the quality control function is usually accomplished by a team of qualified persons with the quality control unit having the overall responsibility and authority to perform a collective, post-processing, final approval.

(Response) The time at which quality control personnel conduct assigned duties will vary by the specific operation, the size and complexity of the operation, and how quality control functions are assigned to qualified

persons. For example, the final rule requires quality control personnel to determine whether components conform to specifications, and to release components from quarantine before you use them in the manufacture of a dietary supplement (final § 111.120). However, this final rule does not require, for example, that quality control personnel determine whether components conform to specifications as soon as you receive them, although it may be common business practice to do so.

Regardless of when quality control personnel perform their operations, quality control personnel have the ultimate responsibility for ensuring manufacturing, packaging, labeling, and holding operations are performed in a manner that will ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.103)

We received many comments that recommend written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to comments on specific provisions in the same section.

Final § 111.103 requires that you establish and follow written procedures for the responsibilities of the quality control operations. Final § 111.103 specifically identifies two of the written procedures you must establish and follow, i.e., written procedures for conducting a material review and making a disposition decision and for approving or rejecting any reprocessing.

E. What Must Quality Control Personnel Do? (Final § 111.105)

Final § 111.105 broadly captures the responsibility of quality control personnel to provide oversight for manufacturing, packaging, labeling, and holding operations. It requires quality control personnel to ensure that your manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.105 derives from proposed § 111.37(a) which would require you to use a quality control unit to ensure your manufacturing, packaging, labeling, and holding operations in the production of dietary supplements are performed in a manner that prevents adulteration and misbranding, including ensuring dietary supplements meet specifications for identity, purity, quality, strength, and composition.

This final rule focuses on ensuring that the manufacturer establishes specifications for its dietary supplements; includes those specifications in the master manufacturing record; meets those specifications and manufactures, packages, labels, and holds the product in a manner that will ensure the quality of the dietary supplement; and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Because of that focus, the labeling requirements of the final rule address the operation of putting the label that is specified in the master manufacturing record on the product rather than the content of a product label that meets all of the labeling requirements of the act and our implementing regulations. The failure to put the label identified in the master manufacturing record on the finished product would be a violation of this final rule. In addition, if the label on the product does not correctly reflect the ingredients, the label would misbrand the product under section 403 of the act. For purposes of this final rule, the labeling operations are CGMP requirements and relate to the label identified in the master manufacturing record. Therefore, we are deleting ''misbranding'' from proposed § 111.37(a) (final § 111.105) since the act of misbranding other than applying a label different from the one identified in the master manufacturing record is not considered a CGMP violation in the context of this final rule. Any misbranding is still a violation of the act, however, and manufacturers must comply with all applicable statutory and regulatory requirements in addition to the requirements of this final rule.

This series of changes emphasizes the need to ensure the quality of a dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. As discussed in detail in the rest of this section, final § 111.105 also requires that quality control personnel perform certain operations and groups of operations.

1. Final § 111.105(a)

Final § 111.105(a) requires that quality control personnel approve or reject all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a dietary supplement. Final § 111.105(a) derives from proposed § 111.37(b)(1).

(Comment 217) One comment recommends revising proposed § 111.37(b)(1) by replacing ''* * * identity, purity, quality, strength, and composition'' with ''* * * identity, purity, quality, strength, or composition.'' The comment asserts the quality control unit must be responsible for approving or rejecting anything that may affect one of these attributes.

(Response) We agree with this comment. Under proposed § 111.37(b)(1) we had intended that the quality control unit be responsible, for example, for approving a test that would establish the identity of a component even if that test did not also establish the strength of that component. Final § 111.105(a) changes ''and'' to ''or'' as requested by this comment.

(Comment 218) One comment recommends the quality control unit be responsible for maintaining the master copies of all current and approved written procedures, for distributing copies of approved written procedures to relevant personnel, and for collecting and destroying outdated Standard Operating Procedures (SOPs) (except designated historical SOP files).

(Response) This comment is consistent with the underlying principle that quality control personnel oversee the design and conduct of the operations associated with the production of a dietary supplement. After considering these comments, final § 111.105(a) requires quality control personnel to approve all written procedures that may affect the identity, purity, strength, or composition of a dietary supplement. With respect to the other suggested duties of quality control personnel, we are leaving the decision as to who performs them, up to the individual firm to best suit its overall operations.

2. Final § 111.105(b), (c), d), and (e)

Final § 111.105(b) requires quality control personnel to review and approve the documentation setting forth the basis for qualification of any supplier. Final § 111.105(c) requires quality control personnel to review and approve the documentation setting forth the basis for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that specifications for the identity, purity, strength, and composition of the dietary supplement are met. Final § 111.105(d) requires quality control personnel to review and approve the documentation setting forth the basis for why the results of appropriate tests or examinations for each product specification selected under final § 111.75(c)(1) will ensure

that the finished batch of the dietary supplement meets product specifications. Final § 111.105(e) requires quality control personnel to review and approve the basis and documentation for why any product specification is exempted from the verification requirements in final § 111.75(c)(1), and for why any component and in-process testing, examination, or monitoring, or other methods will ensure that such exempted product specification is met without verification through periodic testing of the finished batch.

Final § 111.105(b), (c), (d), and (e) are requirements associated with the requirements established in final §§ 111.70(c)(3) and 111.75(a)(ii)(2)(E), (c)(4), (d)(1) and (d)(2).

3. Final § 111.105(f)

Final § 111.105(f) requires quality control personnel to ensure that required representative samples are collected. Final § 111.105(f) differs slightly from proposed § 111.37(b)(11)(i) through (b)(11)(iv) which would require the quality control unit to collect representative samples of incoming materials, in-process materials, each finished batch of dietary supplements, and each batch of packaged and labeled dietary supplements.

After considering comments requesting the quality control unit focus on reviewing tasks performed by others rather than on performing the tasks themselves, the final rule does not specify that quality control personnel must collect representative samples. Under final § 111.105(f), however, quality control personnel retain oversight of sample collection.

4. Final § 111.105(g)

Final § 111.105(g) requires quality control personnel to ensure that required reserve samples are collected and held. Final § 111.105(g) derives from proposed § 111.37(b)(12) which would require the quality control unit to keep reserve samples.

After considering comments requesting the quality control unit focus on reviewing tasks performed by others rather than on performing the tasks themselves, the final rule does not specify that quality control personnel must keep reserve samples. Under final § 111.105(g), however, quality control personnel retain oversight of sample collection and holding.

5. Final § 111.105(h)

Final § 111.105(h) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include determining whether all specifications established in accordance with final § 111.70(a) are met. Final § 111.105(h) derives from proposed § 111.37(b)(2) which would require that the quality control unit determine whether all components, dietary supplements, packaging, and labels conform to specifications. Under the final rule, we are identifying each of the specifications subject to review by quality control personnel under final § 111.77. The requirement for quality control personnel to determine whether specifications established under final § 111.70(a) are met is included for consistency. This requirement is also consistent with final § 111.73 which requires that the production and process control system must include a determination of whether all of the established specifications under final § 111.70(a) are met.

6. Final § 111.105(i)

Final § 111.105(i) requires quality control personnel to perform other operations required under subpart F. Final § 111.105(i) is associated with the reorganization. Under the 2003 CGMP Proposal, proposed § 111.37(a) broadly captured the responsibility of the quality control unit to provide oversight for your manufacturing, packaging, labeling, and holding operations. Proposed § 111.37(b) listed specific operations that we would require the quality control unit to perform. Final § 111.105 now captures the responsibility of quality control personnel to provide oversight for your manufacturing, packaging, labeling, and holding operations. The specific operations that quality control personnel must perform to provide that oversight are set forth in final § 111.105(a) through (h) and in final §§ 111.110, 111.113, 111.117, 111.120, 111.123, 111.127, 111.130, 111.135, and 111.140.

F. What Quality Control Operations Are Required for Laboratory Operations Associated With the Production and Process Control System? (Final § 111.110)

Final § 111.110 sets forth the minimum required operations that quality control personnel must perform with respect to laboratory operations associated with the production and process control system.

1. Final § 111.110(a)

Final § 111.110(a) requires that quality control operations for laboratory operations include reviewing and approving all laboratory control processes associated with the production and process control system. Final § 111.110(a) derives, in part, from proposed § 111.37(b)(9) which would require that the quality control unit review and approve all laboratory control processes. For clarity, we are adding that the laboratory operations covered by final § 111.110 are those associated with the production and process control system. We want to make clear that laboratory operations such as those in your research and development department are not subject to final § 111.110.

We did not receive comments specific to quality control operations under proposed § 111.37(b)(9).

2. Final § 111.110(b)

Final § 111.110(b) requires that quality control operations for laboratory operations associated with the production and process control system include ensuring all tests and examinations required under final § 111.75 are conducted. Final § 111.110(b) derives, in part, from proposed § 111.37(b)(13) which would require the quality control unit to perform appropriate tests and examinations of incoming materials, in-process materials, each finished batch of dietary supplements, and each batch of packaged and labeled dietary supplements.

Proposed § 111.37(b)(13) would list the types of materials that must be tested, including components, packaging, labels, dietary ingredients, and dietary supplements that you receive; the batch production at the in-process and finished batch stages; and packaged and labeled dietary supplements. This list would include materials that, at a minimum, would be tested under the 2003 CGMP Proposal. Under the final rule, the minimum requirements for testing or examination of the materials listed in proposed § 111.37(b)(13) are set forth in final § 111.75. To simplify and clarify proposed § 111.37(b)(13), final § 111.110(b) replaces this list with ''all tests and examinations required under § 111.75.''

3. Final § 111.110(c)

Final § 111.110(c) requires that quality control operations for laboratory operations associated with the production and process control system include reviewing and approving the results of all tests and examinations required under final § 111.75. Final § 111.110(c) derives from proposed § 111.37(b)(9), which would require, in part, that the quality control unit review and approve all testing results. Final § 111.110(c) requires that quality control

personnel review and approve the results of examinations as well as tests. This revision reflects the flexibility provided in the final rule to use either tests or examinations to determine whether specifications are met, provided that the test or examination is an appropriate, scientifically valid method.

As with final § 111.110(b), we provide in final § 111.110(c) that the tests and examinations are those required under final § 111.75.

We did not receive comments specific to quality control operations under proposed § 111.37(b)(9).

G. What Quality Control Operations Are Required for a Material Review and Disposition Decision? (Final § 111.113)

Final § 111.113 derives from several proposed provisions, including §§ 111.35(i), (j), and (n); 111.37(b)(3); 111.40(a)(3) and (b)(2); 111.50(d)(1); 111.65(d); and 111.70(c). All these proposed requirements are related to one or more aspects associated with a material review and disposition, including the circumstances that require a material review and disposition decision, the documentation that must be included in a material review and disposition decision, any restrictions on who must conduct the material review and make the disposition decision, and the need for oversight by the quality control unit. As discussed in section X of this document, we simplified the provisions regarding a material review and disposition decision (final § 111.87), emphasizing the importance of oversight by quality control personnel and retaining the principle that qualified individuals other than those who are designated quality control personnel can contribute to the material review and disposition decision. The final rule sets forth the following requirements for quality control personnel that relate to final § 111.113:

- Under final § 111.87, quality control personnel must conduct all required material reviews and make all required disposition decisions;
- Under final § 111.103, you must establish and follow written procedures for conducting a material review and making a disposition decision; and
- Under final § 111.140(b)(3)(vii), documentation of a material review and disposition decision and followup must include the signature of the individual, designated to perform the quality control operation, who conducted the material review and made the disposition decision and of any qualified individual who provided information relevant to that material review and disposition decision.

The final rule establishes a system in which you have the flexibility to develop procedures that suit your organization, including having qualified individuals, who are not designated to perform the quality control operation, provide information relevant to the material review and disposition decision. For example, under final § 111.140(b)(3), you could have a qualified individual in the production department assist quality control personnel in conducting a material review by preparing a report that includes all the required documentation and information and providing a signed copy of that report to quality control personnel. An individual who is designated to perform the quality control operation could then use that report as part of the material review, conduct any further investigations, as necessary, and decide to accept, amend, or reject the report.

1. Final § 111.113(a)

Under final § 111.113(a) quality control personnel must conduct a material review and make a disposition decision if:

- A specification established in accordance with § 111.70 is not met;
- A batch deviates from the master manufacturing record, including when any step established in the master manufacturing record is not completed and including any deviation from specifications;
- There is any unanticipated occurrence during the manufacturing operations that adulterates or may lead to adulteration of the component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record;
- Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch or batches of a dietary supplement; or
- A dietary supplement is returned.

Final § 111.113(a) is substantially similar to proposed § 111.35(i)(3), which would require, in part, that you make a material disposition decision for any component, dietary supplement, packaging, or label:

- If a component, dietary supplement, packaging, or label fails to meet established specifications;
- If any step established in the master manufacturing record is not completed;
- If there is any unanticipated occurrence during the manufacturing operations that adulterates or may lead to adulteration of the component, dietary supplement, packaging, or label;
- If calibration of an instrument or control suggests a problem that may have caused batches of a dietary supplement to become adulterated; or
- If a dietary supplement is returned.

Final § 111.113(a) also incorporates elements from other proposed sections regarding the circumstances that require a material review and disposition decision as follows:

- Proposed § 111.35(n), which would require you, for any specification that is not met, to conduct a material review and disposition decision under proposed § 111.35(i);
- Proposed § 111.40(a)(3), which would require you, for components, dietary ingredients, or dietary supplements you receive, to conduct a material review and make a disposition decision if specifications are not met;
- Proposed § 111.40(b)(2), which would require that for packaging and labels you receive, you must conduct a material review and make a disposition decision if specifications are not met;
- Proposed § 111.50(d)(1), which would require that if a batch deviates from the master manufacturing record, including any deviation from specifications, the quality control unit must conduct a material review and make a disposition decision and record any decision in the batch production record;
- Proposed § 111.65(d), which would require you to conduct a material review and make a disposition decision in accordance with proposed § 111.35(i) for any component, dietary ingredient, or dietary supplement that fails to meet specifications or that is or may be adulterated; and
- Proposed § 111.70(c), which would require you to conduct a material review and make a disposition decision of any packaged and labeled dietary supplements that do not meet specifications.

In final § 111.113(a) we are incorporating, into a single unified provision, the various proposed circumstances that would require a material review and disposition decision under the 2003 CGMP Proposal. We included revisions associated with final § 111.87 which requires quality control personnel to conduct any required material review and make any required disposition decision. We also included revisions associated with final § 111.90 that relate to the impact on labeling operations due to deviations and unanticipated occurrences.

In establishing final § 111.113(a)(1), we are deleting the specific reference to the articles (components, dietary supplements, packaging, and labels)

required to undergo a material review. We are deleting these references, in part, to simplify the provision. Under final § 111.113(a) quality control personnel must conduct a material review and make a disposition decision if any specification established in accordance with final § 111.70 is not met. It is not necessary to repeat, in final § 111.113, the list of specifications that is clearly set forth in final § 111.70.

We did not receive comments specific to quality control operations under proposed §§ 111.35(i)(3) and (n), 111.40(a)(3) and (b)(2), 111.50(d)(1), 111.65(d), or 111.70(c).

2. Final § 111.113(b)

Final § 111.113(b)(1) requires that, when there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to adulteration of a component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record, quality control personnel must reject the component, dietary supplement, or packaging, or label unless it approves a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence.

Final § 111.113(b)(1) derives from the following proposed provisions:

- Proposed § 111.35(i)(4)(i) which, in part, would require that, for any deviation or unanticipated occurrence which resulted in or could lead to adulteration of the component, dietary ingredient, dietary supplement, packaging, or label, you reject the component, dietary ingredient, dietary supplement, packaging, or label, unless the quality control unit determines that in-process adjustments are possible to correct the deviation or occurrence;
- Proposed § 111.35(i)(4)(ii) which, in part, would require that, for any deviation or unanticipated occurrence which resulted in or could lead to adulteration of the component, dietary ingredient, dietary supplement, packaging, or label, you not reprocess a rejected component or dietary supplement unless approved by the quality control unit; and
- Proposed § 111.37(b)(3) which, in part, would require the quality control unit to approve or reject all dietary ingredients, dietary supplements, components, packaging, and labels.

For consistency with other provisions in final subpart F, final § 111.113(b)(1) requires that quality control personnel ''reject'' a component, dietary supplement, packaging, or label. We also included revisions that are associated with final § 111.90.

Final § 111.113(b)(2) requires that when a specification established in accordance with § 111.70 is not met, quality control personnel must reject the component, dietary supplement, package, or label, unless quality control personnel approve a treatment, an in-process adjustment, or reprocessing, as permitted in final § 111.77. This provision has been added as a result of the new provision, final § 111.77 which provides for what happens when certain specifications are not met, the responsibilities of quality control personnel, and the changes made to final § 111.90.

(Comment 219) Several comments request that the quality control unit focus on reviewing tasks performed by others rather than on performing the tasks itself.

(Response) We agree, and final § 111.113(b) provides that quality control personnel ''approve'' an in-process adjustment rather than ''determine whether'' the in-process adjustment is possible.

3. Final § 111.113(c)

Final § 111.113(c) requires the person who conducts a material review and makes the disposition decision, at the time of performance, to document that material review and disposition decision. Final § 111.113(c) derives from proposed § 111.35(j) which, in part, would require that the person who conducts the material review and makes the disposition decision must, at the time of performance, document every material review and disposition decision in proposed § 111.35(i).

As an editorial revision, final § 111.113(c) requires documentation of ''that'' decision rather than ''every'' decision. As a practical matter, under final § 111.113(c) every material review and disposition decision is documented.

We did not receive comments specific to quality control operations under proposed § 111.35(j).

H. What Quality Control Operations Are Required for Equipment, Instruments, and Controls? (Final § 111.117)

Final § 111.117 (proposed § 111.37(b)(6) through (b)(8)) sets forth the minimum required operations that quality control personnel must perform with respect to equipment, instruments, and controls.

1. Final § 111.117(a) through (c)

Final § 111.117(a) through (c) requires the quality control operations for equipment, instruments, and controls to include:

- Reviewing and approving all processes for calibrating instruments and controls;
- Periodically reviewing all records for calibration of instruments and controls; and
- Periodically reviewing all records for calibrations, inspections, and checks of automated, mechanical, or electronic equipment.

Final § 111.117(a), (b), and (c) derive from proposed § 111.37(b)(6), (b)(7), and (b)(8) which would require the quality control unit to:

- Review and approve all processes for calibrating instruments or controls;
- Review all records for calibration of instruments, apparatus, gauges, and recording devices; and
- Review all records for equipment calibrations, inspections, and checks.

Final § 111.117 includes the following changes we are making for consistency with the requirements, set forth in subpart D, for equipment and utensils:

- We have deleted the terms ''apparatus,'' ''gauges,'' and ''recording devices'' from proposed § 111.37(b)(7) as they would fall under the terms ''instruments and controls'' in final § 111.117, and because subpart D does not use the terms ''apparatus,'' ''gauges,'' or ''recording devices.''
- We are characterizing the records for equipment calibrations, inspections, and checks as records for calibrations, inspections, and checks of ''automated, mechanical, or electronic equipment,'' because final § 111.30(c) requires you to calibrate, inspect, or check ''automated, mechanical, or electronic equipment.''

(Comment 220) One comment argues the requirements for oversight by the quality control unit in proposed § 111.37(b)(7) and (b)(8) are excessive and go beyond requirements for both the drug CGMPs and food CGMPs. The comment recommends revising proposed § 111.37(b)(7) and (b)(8) to require a review of all records when there is a negative impact on the product due to a calibration failure.

Other comments refer to the related requirements in proposed § 111.30(b)(1) that the quality control unit approve calibrations, inspections, or checks of automatic, mechanical, or electronic equipment. These comments assert the requirement for the quality control unit to approve such calibrations, inspections, and checks of equipment is too prescriptive and that qualified persons outside of the quality control unit should be able to approve these calibrations, inspections, or checks. These comments also assert the quality control unit should perform audits of the records generated to ensure the appropriate calibrations, inspections,

and checks are being adequately performed at the required intervals.

(Response) As already discussed with respect to proposed § 111.30(b)(1) (final § 111.30(c)), we disagree that the review by quality control personnel should be limited to circumstances when there has been a calibration failure. One of the oversight functions of quality control personnel is to prevent problems with the product you distribute by finding any problems with the equipment you use to produce the product rather than to investigate the cause of a problem with a product that you already distributed. However, we agree it is sufficient to review the records of calibrations, inspections, and checks of automated, mechanical, or electronic equipment periodically, for example, on an annual basis, rather than to approve each record when it is made. A periodic review can uncover trends in the performance of the equipment that have the potential to adversely affect the quality of the dietary supplement and that may not be obvious by merely approving each record when it is made. Seeing such trends would enable quality control personnel to recommend actions to correct the trend. Therefore, we have revised the proposed requirement so that under final § 111.117(c) quality control personnel must review all records of calibrations, inspections, and checks of automatic, mechanical, or electronic equipment on a periodic basis. Likewise, we have revised the rule so that the quality control personnel's review of all records of equipment calibrations also is on a periodic basis.

(Comment 221) A few comments argue the review of calibration records may be conducted by a qualified person other than the quality control unit, such as by a supervisor or by a separate department dedicated to equipment maintenance and calibration. These comments assert the quality control unit should approve calibration processes, but review of completed calibration records by the dedicated department is sufficient to assure compliance with the approved process.

(Response) As already discussed, many comments about the quality control unit may have misunderstood the proposed definition of ''quality control unit'' (now replaced by ''quality control personnel''). Under final § 111.12(b), you must identify who is responsible for your quality control operations. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations. Thus, in the situation described by these comments, you could identify a qualified person in a department dedicated to equipment maintenance and calibration to perform quality control operations for equipment calibration. Neither the definition of ''quality control personnel,'' nor the requirements of final § 111.12(b), would preclude a person who performs ''Operation X'' from being identified as the person who performs quality control operations for ''Operation X.'' However, we strongly recommend that the person you identify to perform a given quality control operation be a different person than the person who performed the operation that is subject to quality control oversight.

2. Final § 111.117(d)

Final § 111.117(d) requires that quality control operations for equipment, instruments, and controls include reviewing and approving controls to ensure automated, mechanical, or electronic equipment functions in accordance with its intended use. Final § 111.117(d) derives, in part, from proposed § 111.30(b)(4) (final § 111.30(e)) which would require that, for any automated, mechanical, or electronic equipment you use, you must establish and use appropriate controls and the controls are approved by your quality control unit to ensure that the equipment functions in accordance with its intended use. We are clarifying the proposed requirement related to quality control personnel in final § 111.117(d).

We did not receive comments specific to this responsibility of the quality control unit in proposed § 111.30(b)(4).

I. What Quality Control Operations Are Required for Components, Packaging, and Labels Before Use in the Manufacture of a Dietary Supplement? (Final § 111.120)

Final § 111.120 sets forth the minimum required operations that quality control personnel must perform with respect to components, packaging, and labels before use in the manufacture of a dietary supplement. Some of the proposed provisions that form the basis for final § 111.120 included requirements for ''dietary supplements that you receive.'' For example, proposed § 111.40(a) would require you, for components or dietary supplements you receive, to visually examine containers and documentation provided by the supplier, quarantine the materials until they are released by the quality control unit, and identify the materials in a manner that allows you to trace the shipment you receive to the product that you manufacture and distribute. The final rule separates these and other requirements for quality control operations for ''product that you receive from a supplier'' for packaging or labeling as a dietary supplement from the analogous requirements for components. Thus, the requirements for quality control operations for product you receive for packaging and labeling as a dietary supplement (and for distribution rather than for return to the supplier) are found in final § 111.127 rather than final § 111.120.

1. Final § 111.120(a)

Final § 111.120(a) requires that quality control operations for components, packaging, and labels include reviewing all receiving records for components, packaging, and labels before use. Final § 111.120(a) derives from the following proposed provisions:

- Proposed § 111.37(b)(10) which, in part, would require the quality control unit to review and approve all packaging and label records which include, but are not limited to, cross-referencing receiving and batch production records;
- Proposed § 111.40(a)(3) which, in part, would require that you quarantine dietary supplements until your quality control unit reviews the supplier's invoice, guarantee, or certification; and
- Proposed § 111.50(e)(1) which, in part, would require the quality control unit to document its review of component receiving records.

(Comment 222) One comment asserts that the proposed requirement that the review of the batch record by the quality control unit include cross-referencing of receiving records with the batch production record is redundant and should be mandatory only in cases where a specification has not been met. This comment asserts the quality control unit has already reviewed and approved components, packaging, and labels prior to their release and has used unique identifiers for these raw materials as they are recorded on related documentation and records, which allow traceability back to this documentation for review when necessary. This comment also asserts all material review and disposition decisions must be documented and these will include the unique identifiers that tie them to particular raw or in-process materials.

Another comment asserts that the quality control unit should only need to repeat a review of the receiving records as a result of conducting an investigation or a material review, as is required for drugs, and to require

otherwise would be redundant. This comment also states requiring the quality control unit to repeat its review of the receiving records places a fairly large burden on the quality control unit because this re-review must be performed for each and every batch production record. The comments assert the requirement should be completed properly and only once.

(Response) In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12200), we stated that cross-referencing receiving and batch production records means the quality control unit must verify that the batch record includes certain documentation of the receiving records for the components such as the unique identifier assigned to the shipment lot of components, testing results, a material review and disposition decision, if conducted, and approval for use by the quality control unit. We agree with the comments that the review of records such as receiving records (including proper documentation of a unique identifier for components, packaging, and labels), if done properly the first time it is performed, need not be repeated. Therefore, the final rule does not include any requirement for cross-referencing receiving records with the batch production record as we would require under proposed § 111.37(b)(10). As noted, we have changed ''quality control unit'' to ''quality control personnel.'' We agree that cross-referencing receiving and batch production records is an appropriate step to take when conducting a material review and making a disposition when, for example, a specification is not met. We encourage firms to include this activity in the written procedures for conducting a material review and making a disposition decision.

2. Final § 111.120(b)

Final § 111.120(b) requires that quality control operations for components, packaging, and labels include determining whether all components, packaging, and labels conform to specifications established under § 111.70(b) and (d) before use. Final § 111.120(b) derives from proposed § 111.37(b)(2).

We did not receive comments specific to quality control operations under proposed § 111.37(b)(2). For clarity, we have identified the specifications as those required under final § 111.70(b) and (d).

3. Final § 111.120(c)

Final § 111.120(c) requires that quality control operations for components, packaging, and labels include conducting any required material review and making any required disposition decision before use. Final § 111.120(c) derives from the following proposed provisions:

- Proposed § 111.40(a)(3) which, in part, would require you to conduct a material review and make a disposition decision if specifications are not met for components; and
- Proposed § 111.40(b)(2) which, in part, would require you to conduct a material review and make a disposition decision if specifications are not met for packaging and labels.

Final § 111.120(c) includes revisions associated with final § 111.87 which requires quality control personnel to conduct any required material review and make any required disposition decision.

(Comment 223) One comment recommends the quality control unit have authority to allow usage of material that has failed to meet specifications if the defect will not significantly affect the overall quality of the finished product even if reprocessing is not an option. The comment gives an example of a material that fails to meet particle size specifications designed to maximize the efficiency of processing of the material, but ultimately does not impair strength, and asserts the quality unit should have the authority to release the material for use.

(Response) The final rule provides for a process in which quality control personnel determine whether a component meets specifications and conduct a material review and make a disposition decision if a component does not meet one or more specifications. The final rule does not prohibit the use of a component that does not meet all component specifications other than the identity specification. For example, under final § 111.120(d) quality control personnel may approve an in-process adjustment of a component to make it suitable for use in the manufacture of a dietary supplement (see discussion of final § 111.120(d) in the following paragraphs). Under final § 111.123(b) quality control personnel must not approve and release for distribution any batch of dietary supplement, including any reprocessed batch, that does not meet all product specifications or is not a quality product. Thus, although a disposition decision could be made under final § 111.120(c) to use a component even if it does not meet certain specifications, that decision should take into account whether the failure for the component to meet specifications will ultimately cause the dietary supplement to fail to meet product specifications.

4. Final § 111.120(d)

Final § 111.120(d) requires that quality control operations for components, packaging, and labels include approving, or rejecting, any treatment and in-process adjustments of components, packaging, or labels to make them suitable for use in the manufacture of a dietary supplement. Final § 111.120(d) derives from the following proposed provisions:

- Proposed § 111.35(i)(4)(i) which, in part, would require that you reject the component, packaging, or label, unless the quality control unit determines that in-process adjustments are possible to correct the deviation or occurrence and
- Proposed § 111.35(i)(4)(ii) which would have prohibited you from reprocessing a rejected component unless approved by the quality control unit.

Final § 111.120(d) includes a revision associated with final § 111.90(c), and refers to ''treatment and in-process adjustments to make them suitable for use in the manufacture of a dietary supplement'' (see discussion of final § 111.90(c) in section X of this document).

(Comment 224) Several comments request the quality control unit focus on reviewing tasks performed by others rather than on performing the tasks itself.

(Response) Final § 111.120(d) includes a revision that quality control personnel ''approve'' a treatment rather than ''determine that'' the treatment is possible.

(Comment 225) A few comments support the proposed requirement that the quality control unit have the authority to approve reprocessing measures.

(Response) These comments are consistent with proposed § 111.35(i) and (i)(4)(ii) and final § 111.120(d), as applicable to quality control personnel.

(Comment 226) One comment states that the decision to reprocess a material belongs within the particular operational unit, and that the role of the quality control unit should be to approve the results of the reprocessing.

(Response) We disagree that the role of quality control personnel should be limited to approving the results of reprocessing or, in this case, of the treatment or in-process adjustments of components, packaging, or labels. An underlying principle of these CGMP requirements is that quality control personnel oversee the design and conduct of manufacturing, packaging, labeling, and holding operations. A

decision about when reprocessing is, or is not, appropriate requires oversight.

As already discussed, under final § 111.12(b) you must identify who is responsible for your quality control operations. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations.

5. Final § 111.120(e)

Final § 111.120(e) requires that quality control operations for components, packaging, and labels include approving and releasing from quarantine all components, packaging, and labels before they are used. Final § 111.120(e) derives from the following proposed provisions:

- Proposed § 111.40(a)(3) which, in part, would require that you quarantine components until your quality control unit approves the components and releases them from quarantine and
- Proposed § 111.40(b)(2) which, in part, would require that you quarantine packaging and labels until your quality control unit approves the packaging and labels and releases them from quarantine.

We did not receive comments specific to quality control operations under proposed § 111.40(a)(3) or (b)(2).

J. What Quality Control Operations Are Required for the Master Manufacturing Record, the Batch Production Record, and Manufacturing Operations? (Final § 111.123)

Final § 111.123 sets forth the minimum required operations that quality control personnel must perform with respect to the master manufacturing record, the batch production record, and manufacturing operations.

1. Final § 111.123(a)(1)

Final § 111.123(a)(1) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include reviewing and approving all master manufacturing records and all modifications to the master manufacturing records. Final § 111.123(a)(1) derives from duplicate proposed requirements, in proposed §§ 111.37(b)(4) and 111.45(c), with no changes other than the editorial changes associated with the reorganization.

We did not receive comments specific to quality control operations under proposed §§ 111.37(b)(4) or 111.45(c), but have combined them as final § 111.123(a)(1).

2. Final § 111.123(a)(2)

Final § 111.123(a)(2) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include reviewing and approving all batch production-related records. Final § 111.123(a)(2) derives from proposed § 111.37(b)(5), which would require, in part, the quality control unit to review and approve all batch production-related records. Proposed § 111.37(b)(5) explicitly stated, in part, that the batch record would include, but not be limited to, cross-referencing receiving and batch production records.

(Comment 227) One comment expresses concern that proposed § 111.37(b) does not state specifically that the complete batch history, including batch record, analytical records, quality control records, yields, and packaging records should be reviewed and approved by the quality control unit before the batch is shipped. The comment believes these are important requirements that should be clearly stated.

(Response) Proposed § 111.37(b)(5) would require that the quality control unit ''review and approve all batch production-related records, including but not limited to * * *'' We disagree with the comment that this proposed provision would not include what the comment describes. To the extent that the comments interpreted the list of records to mean that only the partial listing of records was required, we have modified final § 111.123(a)(2) to require quality control personnel to review all batch production-related records. We do not emphasize any particular aspect of the batch production record. This reduces the potential to misinterpret the requirement as being limited to the specific items cited.

(Comment 228) As already discussed in detail with respect to final § 111.120(a), some comments assert the proposed requirement that the review of the batch record by the quality control unit include cross-referencing of receiving records with the batch production record is redundant to other requirements that the quality control unit review receiving records for components, packaging, and labels. In general, these comments assert the requirement should be completed properly and only once.

(Response) We agree with the comments that the review of records, such as receiving records, if done properly the first time that it is performed, need not be repeated. Therefore, the final rule does not include any requirements for cross-referencing receiving records with the batch production record as we would require under proposed § 111.37(b)(5).

3. Final § 111.123(a)(3)

Final § 111.123(a)(3) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include reviewing all monitoring required under subpart E. Final § 111.123(a)(3) derives from the following proposed provisions:

- Proposed § 111.35(f) which would require you to monitor the in-process control points, steps, or stages to ensure that specifications established under proposed § 111.35(e) are met and to detect any unanticipated occurrence that may result in adulteration;
- Proposed § 111.35(e)(2) which would require you to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration, including the in-process controls in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary supplements;
- Proposed § 111.35(i)(2) which would require you to review the results of the monitoring required under proposed § 111.35(f) and conduct a material review if an established specification is not met or if there is any unanticipated occurrence that adulterates or could result in adulteration;
- Proposed § 111.35(o)(2) which would require you to make and retain records to ensure you follow the requirements of proposed § 111.35, including the actual results obtained during the monitoring operation; and
- Proposed § 111.37(b)(5) which would require the quality control unit to review and approve all batch production-related records.

Under the final rule, the results of the monitoring required under proposed § 111.35(f) must be kept in the batch record (see the discussion of the batch record in section XIV of this document). Quality control personnel must review the results of the required monitoring.

(Comment 229) One comment suggests the phrase ''review the results of the monitoring required by this section'' be deleted from proposed § 111.35(i)(2) because it is unnecessary and can be read as narrowing any final rule. This comments points out the only required monitoring in the proposal appears in § 111.35(f) related to

monitoring of in-process control points, steps, or stages, and that such monitoring would not necessarily find all failures in specifications, for example, specifications related to raw materials or labels.

(Response) We disagree with the comment that the quoted language narrows the final rule. Monitoring that relates to in-process control points, steps, or stages would be required under proposed § 111.35(f) and is now required in final § 111.123(a)(3). However, in practice, a manufacturer must monitor its entire operation to ensure that the requirements of the final rule are met. For example, under final § 111.73, a manufacturer must determine whether specifications established under final § 111.70 are met and under final § 111.75(a) and (f) a manufacturer must use certain criteria to determine whether specifications for components and labels, respectively, are met. Thus, there are sufficient controls in other requirements to ensure the entire production and process controls are functioning as intended.

4. Final § 111.123(a)(4)

Final § 111.123(a)(4) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include conducting any required material review and making any required disposition decision. Final § 111.123(a)(4) derives from the following proposed provisions:

- Proposed § 111.37(b)(5) which, in part, would require the quality control unit to approve a material review and disposition decision related to batch production records; and
- Proposed § 111.50(d)(1) which, in part, would require, if a batch deviates from the master manufacturing record, including any deviation from specifications, the quality control unit to conduct a material review and make a disposition decision.

We did not receive comments specific to quality control operations under proposed §§ 111.37(b)(5) or 111.50(d)(1).

5. Final § 111.123(a)(5)

Final § 111.123(a)(5) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include approving or rejecting any reprocessing. Final § 111.123(a)(5) derives from proposed § 111.37(b)(5) which would require the quality control unit to approve any reprocessing. For consistency with other provisions in this final rule (such as final § 111.90), final § 111.123(a)(5) includes a revision that quality control personnel must approve—or reject—any reprocessing.

We did not receive comments specific to quality control operations under proposed § 111.37(b)(5).

6. Final § 111.123(a)(6)

Final § 111.123(a)(6) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include determining whether all in-process specifications established in accordance with § 111.70(c) are met. Final § 111.123(a)(6) derives from the following proposed provisions:

- Proposed § 111.35(f) which would require you to monitor the in-process control points, steps, or stages to ensure specifications are met (including the in-process specifications required under proposed § 111.35(e)(2)) and
- Proposed § 111.37(a) which, in part, would require the quality control unit to ensure your manufacturing, packaging, labeling, and holding operations are performed in a manner that prevents adulteration, including that such operations ensure the dietary supplement meets its specifications for identity, purity, quality, strength, and composition.

Final § 111.123(a)(6) is consistent with the overall approach, set forth in final §§ 111.70, 111.73, and 111.75, that focuses on ensuring the quality of the dietary supplement throughout the production and process control system.

We did not receive comments specific to quality control operations under proposed §§ 111.35(e)(2) or (f), or 111.37(a).

7. Final § 111.123(a)(7)

Final § 111.123(a)(7) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include determining whether each finished batch conforms to product specifications established in accordance with final § 111.70(e). Final § 111.123(a)(7) derives from proposed § 111.37(b)(2) which, in part, would require the quality control unit to determine whether all dietary supplements conform to specifications.

We did not receive comments specific to quality control operations under proposed § 111.37(b)(2).

8. Final § 111.123(a)(8)

Final § 111.123(a)(8) requires that quality control operations for the master manufacturing record, the batch production record, and manufacturing operations include approving and releasing, or rejecting, each finished batch for distribution, including any reprocessed finished batch. Final § 111.123(a)(8) derives from the following proposed provisions:

- Proposed § 111.37(b)(5) which, in part, would require the quality control unit to approve batch production records for releasing finished batches for distribution;
- Proposed § 111.50(d)(2) which would require the quality control unit to not approve and release for distribution any batch that does not meet all specifications; and
- Proposed § 111.50(g) which would require the quality control unit to not approve and release for distribution any reprocessed batch of dietary supplement that does not meet all specifications.

We did not receive comments specific to the proposed provisions cited above.

9. Final § 111.123(b)

Final § 111.123(b) requires that quality control personnel must not approve and release for distribution:

- any batch of dietary supplement for which any component in the batch does not meet its identity specification;
- any batch of dietary supplement, including any reprocessed batch, that does not meet all product specifications established in accordance with § 111.70(e);
- any batch of dietary supplement, including any reprocessed batch, that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act; and
- any product received from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for which sufficient assurance is not provided to adequately identify the product and to determine that the product is consistent with your purchase order.

Final § 111.123(b) derives from the following proposed provisions:

- Proposed § 111.50(d)(2) which would require the quality control unit to not approve and release for distribution any batch of dietary supplement that does not meet all specifications;
- Proposed § 111.50(g) which would require that a reprocessed batch of dietary supplement meet all specifications and that the quality control unit approve its release for distribution; and
- Proposed § 111.37(b)(11)(iii) which would require the quality control unit to collect representative samples of each batch of dietary supplement manufactured to determine, before releasing for distribution, whether the dietary supplement meets its

specifications for identity, purity, quality, strength, and composition.

The final provision clarifies all of the responsibilities of quality control personnel and includes provisions consistent with changes made to final §§ 111.73, 111.77, and 111.90.

We did not receive comments specific to those aspects of proposed §§ 111.50(g) and 111.37(b)(11)(iii) that are relevant to final § 111.123(b). We discuss in the following paragraphs comments we received to proposed § 111.50(d)(2).

(Comment 230) Several comments object to proposed § 111.50(d)(2) because it would prohibit the release of any batch that does not meet all specifications. Other comments suggest the prohibition should apply to meeting ''release specifications'' or ''essential manufacturer specifications'' rather than ''all specifications'' because in-process deviations and minor deviations may not affect product quality.

(Response) A finished dietary supplement that is ready for release for distribution must meet component specifications for identity established under final § 111.70(b) and all product specifications established for the batch under final § 111.70(e) and must be manufactured in a manner to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act. The final rule does not prevent you from establishing additional specifications that do not affect the identity, purity, strength, composition, or contaminant levels of your finished dietary supplement. Such a specification is not a component specification for identity or a product specification that is required under the final rule. Final § 111.123(b) would not preclude you from releasing a product that fails to meet a specification that is not a component specification for identity or a product specification established under final § 111.70 provided quality control personnel approve such release. Final § 111.123(b) would not preclude you from releasing a product that you are permitted to release under final § 111.77.

(Comment 231) Some comments note that proposed § 111.50(d)(2) would not allow the quality control unit to conduct an investigation, and make a disposition decision, of the failure of a batch to meet specifications. These comments assert proposed § 111.50(d)(2) therefore restricts the provision in proposed § 111.50(d)(1) which would require that, if a batch deviates from the master manufacturing record, including any deviation from specifications, the quality control unit must conduct a material review and make a disposition decision. The comments argue the quality control unit should have the authority to release products with minor deviations.

(Response) As discussed previously (see discussion of final § 111.90 in subpart E in section X of this document), we acknowledge that some specifications, such as component, other than for identity, and in-process specifications, that are not met may be able to be corrected by a treatment or an in-process adjustment. Quality control personnel would need to conduct a material review and disposition decision for any such specification not met. If there are specifications for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record (final § 111.70(a)), you must determine whether these specifications are met (final § 111.73).

Final § 111.123(b) does not preclude you, for example, from releasing a product that was the subject of a material review because sampling procedures had not been followed if, as a corrective action, the appropriate samples were collected and subjected to appropriate tests and examinations.

K. What Quality Control Operations Are Required for Packaging and Labeling Operations? (Final § 111.127)

Final § 111.127 sets forth the required operations that quality control personnel must perform with respect to packaging and labeling operations.

1. Final § 111.127(a) and (b)

Final § 111.127(a) and (b) set forth requirements for product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier).

Final § 111.127(a) and (b) apply to product that has left the control of the person who manufactured the batch; for example, the purchase of dietary supplements in bulk for packaging or labeling by a person who will distribute the packaged and labeled dietary supplements under a private label. If you are a packager or labeler who operates under contract to the manufacturer, and you will return the dietary supplement to the manufacturer, we would not consider that you are ''receiving'' product within the meaning of final § 111.127(a) and (b). We would consider you to be no different than an operating unit of the manufacturer. In section VI of this document (subpart A), we discuss in detail the scope of this final rule and its applicability to contractors.

a. *Final § 111.127(a).* Final § 111.127(a) requires that quality control operations for packaging and labeling operations include reviewing the results of any visual examination and documentation to ensure that specifications established under final § 111.70(f) are met for product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier). Final § 111.127(a) derives from the following proposed provisions:

- Proposed § 111.40(a)(2) which would require you to visually examine the supplier's invoice, guarantee, or certification to ensure that dietary supplements you receive are consistent with your purchase order and perform testing, as needed, to determine whether specifications are met and
- Proposed § 111.40(a)(3) which would, in part, require you to quarantine dietary supplements you receive until your quality control unit reviews the supplier's invoice, guarantee, or certification and performs testing, as needed, of a representative sample to determine that specifications are met.

Final § 111.127(a) includes revisions associated with final §§ 111.70(f) and 111.75(e) which set forth requirements for all products you receive from a supplier for packaging or labeling as dietary supplements (and for distribution rather than for return to the supplier). As discussed in section X of this document, under final § 111.70(f) if you receive such product, you must establish specifications to provide sufficient assurance that the product you receive is adequately identified and is consistent with your purchase order. In addition, under final § 111.75(e) before you package or label such products, you must visually examine the products and have documentation to determine whether the specifications that you established under final § 111.70(f) are met. The documentation you have to satisfy the requirements of final § 111.75(e) is not limited to a supplier's invoice, guarantee, or certification and, thus, final § 111.127(a) incorporates the standard set by final § 111.75(e) (i.e., documentation) rather than the proposed standard of the supplier's invoice, guarantee, or certification. In addition, consistent with final § 111.75(e), final § 111.127(a) requires quality control personnel to review the results of the visual examination but not otherwise review the results of tests or examinations.

We did not receive comments specific to quality control operations under proposed § 111.40(a)(2) or (a)(3).

b. *Final § 111.127(b).* Final § 111.127(b) requires that quality control operations for packaging and labeling operations include approving, and releasing from quarantine, all products you receive for packaging and labeling as a dietary supplement (and for distribution rather than for return to the supplier) before the products are used for packaging and labeling. Final § 111.127(b) derives from proposed § 111.40(a)(3) which, in part, would require you to quarantine dietary supplements that you receive until your quality control unit reviews the supplier's invoice, guarantee, or certification and performs testing, as needed, of a representative sample to determine that specifications are met, and approves and releases the dietary supplements from quarantine before you use them.

As with final § 111.127(a), final § 111.127(b) includes revisions associated with changes made in final §§ 111.70(f) and 111.75(e).

We did not receive comments specific to quality control operations under proposed § 111.40(a)(3).

2. Final § 111.127(c)

Final § 111.127(c) requires that quality control operations for packaging and labeling operations include reviewing and approving all records for packaging and label operations. Final § 111.127(c) derives from proposed § 111.37(b)(10) which, in part, would require the quality control unit to review and approve all packaging and label records.

We did not receive comments specific to quality control operations under proposed § 111.37(b)(10).

3. Final § 111.127(d)

Final § 111.127(d) requires that quality control operations for packaging and labeling operations include determining whether the finished packaged and labeled dietary supplement conforms to specifications established in accordance with final § 111.70(g). Final § 111.127(d) derives from the following proposed provisions:

- Proposed § 111.37(b)(2) which, in part, would require the quality control unit to determine whether all dietary supplements conform to specifications and
- Proposed § 111.37(b)(11)(iv) which, in part, would require the quality control unit to collect representative samples of each batch of packaged and labeled dietary supplements to determine that you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record.

For clarity, final § 111.127(d) identifies the specifications as those established in final § 111.70(g).

We did not receive comments specific to quality control operations under proposed § 111.37(b)(2) or (b)(11)(iv).

4. Final § 111.127(e)

Final § 111.127(e) requires that quality control operations for packaging and labeling operations include conducting any required material review and making any required disposition decision. Final § 111.127(e) derives from the following proposed provisions:

- Proposed § 111.70(c) which would require you to conduct a material review and make a disposition decision of any packaged and labeled dietary supplement that does not meet specifications and
- Proposed § 111.40(a)(3) which, in part, would require you, if specifications are not met for a received dietary supplement, to conduct a material review and make a disposition decision.

Final § 111.127(e) includes revisions associated with final § 111.87 which requires quality control personnel to conduct any required material review and make any required disposition decision.

We did not receive comments specific to quality control operations under proposed §§ 111.70(c) or 111.40(a)(3).

5. Final § 111.127(f) and (g)

Final § 111.127(f) requires that quality control operations for packaging and labeling operations include approving or rejecting any repackaging of a packaged dietary supplement. Final § 111.127(g) requires that quality control operations for returned dietary supplements include approving or rejecting any relabeling of a packaged and labeled dietary supplement. Final § 111.127(f) and (g) derive from the following proposed provisions:

- Proposed § 111.37(b)(10) which, in part, would require the quality control unit to approve any repackaging and relabeling and
- Proposed § 111.70(d) which would require the quality control unit to approve and document any repackaging or relabeling of a dietary supplement.

For consistency with other provisions in this final rule (such as final § 111.90), final § 111.127(f) and (g) provide that quality control personnel must clearly choose between approving—or rejecting—any repackaged or relabeled dietary supplements.

We did not receive comments specific to quality control operations under proposed §§ 111.37(b)(10) or 111.70(d).

6. Final § 111.127(h)

Final § 111.127(h) requires that quality control operations for packaging and labeling operations include approving for release, or rejecting, any packaged and labeled dietary supplement (including a repackaged or relabeled dietary supplement) for distribution. Final § 111.127(h) derives from the following proposed provisions:

- Proposed § 111.37(b)(10) which, in part, would require the quality control unit to approve the release of packaged and labeled dietary supplements for distribution; and
- Proposed § 111.70(e) which, in part, would require the quality control unit to approve or reject the release of any repackaged or relabeled dietary supplement.

We did not receive comments specific to quality control operations under proposed §§ 111.37(b)(10) or 111.70(e).

L. What Quality Control Operations Are Required for Returned Dietary Supplements? (Final § 111.130)

Final § 111.130 sets forth the minimum required operations quality control personnel must perform with respect to returned dietary supplements.

Final § 111.130 modifies proposed § 111.85 which set forth requirements for returned dietary ingredients and dietary supplements, including requirements for quality control operations for returned dietary supplements. We did not explicitly include quality control operations with respect to returned dietary supplements under proposed § 111.37 but did include quality control operations in proposed § 111.85 for returned dietary supplements. The provisions of the final rule that pertain to returned dietary supplements are set forth in final subpart N. However, we are duplicating these requirements in subpart F to make clear that once returned products are back within your control, quality control personnel must perform appropriate operations before the products are redistributed, if they are approved for redistribution. Any returned dietary supplements that are reprocessed must be returned to your production and process control system, and, therefore, must be properly reviewed by quality control personnel.

1. Final § 111.130(a)

Final § 111.130(a) requires that quality control operations for returned dietary supplements include conducting any required material review and

making any required disposition decision. Final § 111.130(a) differs slightly from proposed § 111.85(a) which, in part, would require the quality control unit to conduct a material review and make a disposition decision for any returned dietary supplement.

(Comment 232–233) Some comments support the proposed requirement to specify that it is the quality control unit that conducts the material review and makes the disposition decision regarding returned dietary supplement products.

(Response) These comments are consistent with proposed § 111.85(a) which is being incorporated into final § 111.130(a).

2. Final § 111.130(a)(1) and (a)(2)

Final § 111.130(a)(1) requires that quality control operations for returned dietary supplements include determining whether tests or examination are necessary to determine compliance with product specifications established in accordance with final § 111.70(e).

Final § 111.130(a)(2) requires that the review and disposition decision for returned dietary supplements include review of the results of any tests or examinations that are conducted to determine compliance with product specifications established in accordance with final § 111.70(e).

3. Final § 111.130(b)

Final § 111.130(b) requires that quality control operations for returned dietary supplements include approving or rejecting any salvage and redistribution of any returned dietary supplement. Final § 111.130(b) derives from proposed § 111.37(b)(15) which, in part, would require the quality control unit to approve the distribution of returned dietary supplements. As discussed in the preamble to the 2003 CGMP Proposal, ''salvage'' means to return to distribution without reprocessing (68 FR 12157 at 12215).

For consistency with other regulations in this final rule (such as final § 111.90), final § 111.130(e) provides that quality control personnel must clearly choose between approving—or rejecting—any salvage and redistribution.

(Comment 234) Some comments support the proposed requirement to specify that it is the quality control unit who approves, or rejects, a returned dietary supplement for redistribution.

(Response) These comments are consistent with proposed § 111.37(b)(15) which is being incorporated into final § 111.130(b).

4. Final § 111.130(c)

Final § 111.130(c) requires that quality control operations for returned dietary supplements include approving or rejecting any reprocessing of any returned dietary supplement. Final § 111.130(c) derives from proposed § 111.37(b)(15) which, in part, would require the quality control unit to approve the reprocessing of returned dietary supplements. For consistency with other provisions of this final rule (such as final § 111.90), final § 111.130(c) provides that quality control personnel must clearly choose between approving—or rejecting—any reprocessing.

(Comment 235) One comment argues that the responsibility to decide whether a returned dietary supplement is reprocessed belongs with qualified persons in manufacturing operations, and the only responsibility of the quality control unit is to approve the reprocessed product for distribution.

(Response) We disagree with the comment. An underlying principle of these CGMP requirements is that quality control personnel oversee the design and conduct of manufacturing, packaging, labeling, and holding operations. A decision about when reprocessing is, or is not, appropriate requires oversight.

5. Final § 111.130(d)

Final § 111.130(d) requires that quality control operations for returned dietary supplements include determining whether the reprocessed dietary supplement meets product specifications and either approving for release, or rejecting, any returned dietary supplement that is reprocessed. Final § 111.130(d) derives from the following proposed provisions:

- Proposed § 111.37(b)(2) which, in part, would require the quality control unit to determine whether all dietary supplements conform to specifications; and
- Proposed § 111.65(d) which, in part, would require you, if a material review and disposition decision allows you to reprocess a dietary supplement, to ensure it meets specifications and is approved by the quality control unit.

For consistency with other regulations in this final rule (such as final § 111.90), final § 111.130(d) provides that quality control personnel must clearly choose between approving—or rejecting—a reprocessed dietary supplement.

We did not receive comments specific to quality control operations under proposed §§ 111.37(b)(2) or 111.65(d).

M. What Quality Control Operations Are Required for Product Complaints? (Final § 111.135)

Final § 111.135 requires that quality control operations for product complaints include reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings and followup action of any investigation performed.

Final § 111.135 derives from proposed § 111.95 which would set forth requirements for consumer complaints (now ''product complaints''), including requirements for quality control operations for consumer complaints. We did not explicitly include quality control operations with respect to consumer complaints under proposed § 111.37 but did include quality control operations in proposed § 111.95 for review and investigation of consumer complaints. The final rule's product complaint requirements are now set forth in final subpart O. However, we have duplicated the requirements for quality control operations for product complaints in subpart F to make clear that your investigation of the product complaint has the potential to uncover a problem with your production and process control system and, therefore, quality control personnel must exercise appropriate oversight of your investigation of any product complaint.

N. What Records Must You Make and Keep? (Final § 111.140)

Final § 111.140 sets forth the requirements for records that quality control personnel must make and keep.

1. Final § 111.140(a)

Final § 111.140(a) requires quality control personnel to make and keep records required under subpart F in accordance with subpart P. Final § 111.140(a) derives from proposed § 111.37(d) with editorial revisions associated with the reorganization.

Other than comments that generally opposed the requirements to make and keep records, and to have records available for inspection and copying by FDA when requested (see the discussion in section V of this document), we did not receive comments specific to proposed § 111.37(d).

2. Final § 111.140(b)(1)

The final rule (final § 111.103) requires you to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision and for approving or rejecting

reprocessing. The written procedures are records. Therefore, final § 111.140(b)(1) requires you to make and keep a record of the written procedures for the responsibilities of the quality control operations.

3. Final § 111.140(b)(2)

Final § 111.140(b)(2) requires written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements under subpart F. Final § 111.140(b)(2)(i) requires quality control personnel to record the date that the review, approval, or rejection was performed. Final § 111.140(b)(2)(ii) requires quality control personnel to record the signature of the person performing the review, approval, or rejection. Final § 111.140(b)(2) derives from proposed § 111.37(c) with revisions associated with the reorganization.

We did not receive comments specific to proposed § 111.37(c).

4. Final § 111.140(b)(3)

Final § 111.140(b)(3) requires quality control personnel to document any material review and disposition decision and followup and include the documentation in the batch record. Final § 111.140(b)(3) derives from proposed § 111.35(j) with revisions associated with the reorganization and a revision, associated with final § 111.87 which requires quality control personnel to conduct the material review and make the disposition decision.

Final § 111.140(b)(3) details the type of information that must be included as part of this documentation. Five paragraphs derive from proposed § 111.35(j)(1) through (j)(5), with editorial changes associated with the reorganization. One paragraph is associated with final § 111.90(b) which requires that you not reprocess any component or dietary supplement that is rejected or treat a component or make an in-process adjustment to make it suitable for use in the manufacture of a dietary supplement, unless quality control personnel conduct a material review and make a disposition decision that is based on a scientifically valid reason and approve the reprocessing, treatment, or in-process adjustment. Another paragraph derives, in part, from proposed § 111.37(c)(2) which would require the signature of the quality control unit person performing the requirement.

The documentation that must be included under final § 111.140(b)(3) is as follows:

- Section 111.140(b)(3)(i)—Identification of the specific deviation or the unanticipated occurrence;
- Section 111.140(b)(3)(ii)—A description of your investigation into the cause of the deviation from the specification or the unanticipated occurrence;
- Section 111.140(b)(3)(iii)—An evaluation of whether the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the dietary supplement or a failure to package and label the dietary supplement as specified in the master manufacturing record;
- Section 111.140(b)(3)(iv)—Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or the unanticipated occurrence;
- Section 111.140(b)(3)(v)—An explanation of what you did with the component, dietary supplement, packaging, or label;
- Section 111.140(b)(3)(vi)—A scientifically valid reason for any reprocessing of a dietary supplement that is rejected, or the treatment or in-process adjustment of a component that is rejected; and
- Section 111.140(b)(3)(vii)—The signature of the individual(s) designated to perform the quality control operation, who conducted the material review and made the disposition decision, and of each qualified individual who provided information relevant to that material review and disposition decision.

We did not receive comments specific to proposed § 111.35(j).

XII. Comments on the Production and Process Control System: Requirements for Components, Packaging, and Labels, and for Product that You Receive for Packaging or Labeling as a Dietary Supplement (Final Subpart G)

A. Organization of Final Subpart G

In the 2003 CGMP Proposal, the requirements for production and process controls related to components, packaging, dietary ingredients, labels, and dietary supplements that you receive were set forth in proposed § 111.40. As shown in table 8 of this document, we are reorganizing the requirements related to components, packaging, labels, and product that you receive for packaging and labeling as a dietary supplement, into a distinct subpart (final Subpart G—Production and Process Control System: Requirements for Components, Packaging, and Labels, and for Product that You Receive for Packaging or Labeling as a Dietary Supplement). Table 8 lists the sections in final subpart G and identifies the sections in the 2003 CGMP Proposal that form the basis of the final rule.

TABLE 8.—DERIVATION OF SECTIONS IN FINAL SUBPART G

Final Rule	2003 CGMP Proposal
§ 111.153 What Are the requirements under this subpart G for written procedures?	N/A
§ 111.155 What requirements apply to components of dietary supplements?	§ 111.40(a)(1) through (a)(5) § 111.35(d)(1) throug (d)(5)
§ 111.160 What requirements apply to packaging and labels received?	§ 111.35(e)(4) § 111.40(a)(2) and (b)
§ 111.165 What requirements apply to a product received for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier)?	§ 111.40(a)
§ 111.170 What requirements apply to rejected components, packaging, and labels, and to rejected products that are received for packaging or labeling as a dietary supplement?	§ 111.74
§ 111.180 Under this subpart G, what records must you make and keep?	§ 111.40(c)(1)(i) through (c)(1)(iv) and (c)(2) § 111.35(d)(4)

B. Highlights of Changes to the Proposed Requirements for Components, Packaging, and Labels, and Product That You Receive for Packaging or Labeling as a Dietary Supplement

1. Revisions

The final rule:

- Applies to persons who manufacture, package, label, or hold a dietary supplement unless subject to an exclusion in § 111.1.
- Includes requirements that apply to components, including components that are dietary ingredients, regardless of whether you receive the components or manufacture them yourself (final §§ 111.70(b) and 111.75(a)).
- Separates the requirements for product you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather

than for return to the supplier) (final § 111.165) from the requirements for components (final § 111.155).

2. Changes After Considering Comments

The final rule incorporates a new requirement to establish and follow written procedures for fulfilling the requirements for components, packaging, labels, and product you receive from a supplier for packaging or labeling as a dietary supplement for distribution rather than for return to the supplier.

C. General Comments on Proposed § 111.40 (Final Subpart G)

(Comment 236) One comment states that many companies use an electronic material resource planning system to control the status of inventory, and assert this type of system provides suitable controls to ensure only materials that are approved by the quality control unit are used. The comment notes only the quality control unit has the authority to release any material in quarantine and asks whether such a system would comply with the requirements of the proposed regulation.

(Response) Based on the limited information provided by the comment, it appears the electronic inventory system that the comment describes would comply with the requirements of final § 111.155(c)(3) to quarantine components until quality control personnel release them for use in manufacture, provided that appropriate controls are established and used to ensure the system functions in accordance with its intended use as required by final § 111.30(e). We are making no changes based on this comment.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.153)

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section.

Final § 111.153 requires you to establish and follow written procedures for fulfilling the requirements of subpart G. Under final § 111.180(b)(1), as a conforming requirement, we require you to make and keep records of such written procedures. Such records would be available to us under the requirements in Subpart P—Records and Recordkeeping.

E. What Requirements Apply to Components of Dietary Supplements? (Final § 111.155)

The final rule applies only to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion under final § 111.1. The effect of this revision is that the requirements that derive from proposed § 111.40(a) for components you receive now apply to all components, whether you receive them or manufacture them yourself.

The final rule separates the requirements for product you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) (final § 111.165) from the analogous requirements for components, packaging, and labels (final § 111.155).

1. Proposed § 111.35(d)

In proposed § 111.35(d), we would require that any substance, other than a ''dietary ingredient'' within the meaning of section 201(ff) of the act, that is subject to section 409 of the act, be: (1) Authorized for use as a food additive under section 409 of the act; or (2) authorized by a prior sanction consistent with § 170.3(l) (21 CFR 170.3(l)); or (3) if used as a color additive, subject to a listing that, by the terms of that listing (including a listing for use in coloring foods generally), includes the use in a dietary supplement; or (4) GRAS for use in a dietary supplement. We also proposed that any claim that a substance is GRAS must be supported by a citation to the agency's regulations or by an explanation for why there is general recognition of safety of the use of the substance in a dietary supplement. Further, under § 111.35(d)(5), we proposed to require that you comply with all other applicable statutory and regulatory requirements under the act.

We received several comments objecting to one or more of the provisions of proposed § 111.35(d) and to our statement in the preamble to the 2003 CGMP Proposal regarding how we would apply the provisions of proposed § 111.35(d)(4). After considering these comments, we have deleted the requirements in § 111.35(d) in this final rule.

(Comment 237) Several comments recommend proposed § 111.35(d) be deleted because the statute already requires that ingredients, other than ''dietary ingredients,'' be approved as a food additive or a color additive, or be GRAS. Some comments assert that proposed § 111.35(d) and proposed § 111.5 already require compliance with all other applicable statutory and regulatory requirements under the act, and therefore, there is no need to refer to food additive, color additive, and GRAS requirements. Some comments assert that proposed § 111.35(d) is unnecessary because there is no such requirement in the food CGMPs. Other comments assert this proposed requirement should be deleted because it is only tangentially related to the manufacturing process, and CGMP should be focused on setting minimum standards for manufacturing systems and steps in the production and distribution of dietary supplements that are required to produce safe and accurately labeled products. Other comments assert that because the drug CGMPs do not have such a requirement, dietary supplement CGMPs should not have such a requirement.

Other comments did not object to the principle underlying proposed § 111.35(d), i.e., that we need to ensure GRAS substances used in dietary supplements are GRAS under the manufacturer's specified use. However many comments disagreed, for various reasons, with the proposed requirement in § 111.35(d)(4) that a claim that a substance is GRAS must be supported by a citation to our regulations or by an explanation for why there is general recognition of safety of the use of the substance in a dietary supplement.

(Response) We agree that proposed § 111.35(d) is unnecessary because there are already existing statutory and regulatory requirements related to the lawful use of ingredients used in dietary supplements. We do not have to repeat those requirements in this final rule. Ensuring the ingredients you use to manufacture a dietary supplement are lawful under the applicable statutory and regulatory requirements is the responsibility of the dietary supplement manufacturer.

For the reasons set forth in the previous paragraphs, we are deleting proposed § 111.35(d)(4) from the final rule. Because we are deleting this provision, it is unnecessary to respond to the various comments related to the documentation that proposed § 111.35(d)(4) would have required, or whether we could not have included such requirements in the dietary supplement CGMP final rule because the requirements are not in food or drug CGMP regulations.

We also agree that proposed § 111.35(d)(5) is redundant to proposed § 111.5 and final § 111.5 and are therefore not repeating proposed § 111.35(d)(5) in final § 111.35.

Although we are deleting § 111.35(d) from the final rule, there were several

comments that we received, and respond to in the following paragraphs, that seemed to question whether existing statutory and regulatory requirements apply to the use of ingredients in a dietary supplement.

(Comment 238) One comment suggests components not found in finished goods in a material amount should not be subject to the same GRAS requirements as those found in a material amount. Another comment states dietary supplements are excluded from the food additive definition in section 201(s) of the act, and that components that constitute the dietary supplement are also excluded from the food additive definition. The comment suggests that, under proposed § 111.35(d), we are erroneously trying to maintain food additive authority for dietary supplements.

(Response) The assertion that dietary supplements and all of their components are not subject to the food additive provisions of the act's definition is incorrect. We do maintain authority over the use of certain substances, as color additives, food additives,[10] or GRAS substances that may be used in manufacturing dietary supplements.

The food additive definition in section 201(s) of the act excludes ''an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.'' Thus, a ''dietary ingredient'' described in section 201(ff)(1) of the act is not a ''food additive.'' Nor can the use of a dietary ingredient be considered to be GRAS, since the GRAS status itself is an exception to the definition of a food additive. However, ingredients that may be used in a dietary supplement, other than those excepted in section 201(s), are subject to our regulatory authority as a food additive, unless their use is GRAS or authorized by a prior sanction. Thus, it is incorrect to say, as the comment asserts, that dietary supplements and all of their components are not subject to the food additive definition.

We also disagree that components not found in finished goods in a material amount should not be subject to the same GRAS requirements as those found in a material amount. It is not clear what the comment meant by ''material amount.'' A food additive means ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food'' if the use of such substance is not GRAS (section 201(s) of the act).[11] We have discretion to determine whether an ingredient is one where the agency would find the presence to be ''de minimis'' (*Monsanto* v. *Kennedy*, 613 F.2d 947, 956 (D.C. Cir. 1979)). However, whether the agency would find it appropriate to exercise such discretion with respect to the use of a particular ingredient is beyond the scope of this final rule.

(Comment 239) Several comments questioned whether certain ingredients would be considered GRAS. One comment stated excipients regularly used in pharmaceuticals for many years and safely used in dietary supplements may not be considered GRAS for use in foods, approved for use as a food additive, or considered a dietary ingredient. An example provided was ''croscarmellose sodium'' used for disintegration. The comment asks permission to use any recognized excipient, an excipient that is monographed in a recognized compendium, used in drug products, or shown to be in use prior to the implementation of the final rule. Other comments stated proposed § 111.35(d) would be overly burdensome since many ingredients are GRAS for broad food use, have been used in dietary supplements without specific recognition as a GRAS use, and should be permitted. Other comments state substances listed in the USP National Formulary, Food Chemical Codex, the American Pharmaceutical Associations Handbook of Pharmaceutical Excipients, and FDA's inactive ingredient guide are considered GRAS based on a history of common use even though there is no listing of these substances as GRAS.

(Response) The GRAS status of specific uses of excipients cannot be treated as a general class and is beyond the scope of this final rule. It is possible that the data needed to support safe uses as an excipient in a drug may be widely known among experts and form a basis for a consensus that use in a dietary supplement is safe. However, use of drugs containing the excipient may be short term or may be intermittent, leading to far less exposure than routine use in some dietary supplements. As human exposure increases, not only does the safety profile of the intended excipient become more important, but the purity specifications also become more critical. We advise persons who need more information about the basis for concluding that a use of a substance is GRAS to consult § 170.30 and our GRAS Proposal to establish a notification program for the use of GRAS substances (62 FR 18938, April 17, 1997).

(Comment 240) Some comments assert it is not feasible to require that starting materials used by bulk ingredient manufacturers be GRAS or approved food additives. The comments state many ingredients are not food grade substances or approved for use in food until after processing. One comment states raw materials may become dietary ingredients after processing, but the materials from which the dietary ingredient is derived are not considered to be a GRAS ingredient, a dietary ingredient, or a dietary supplement. The comment gives examples of Ginkgo biloba leaves or Saw palmetto or cartilage. The comment asks us to consider natural products (from animal, mineral, or vegetable origin) to be included in the rule as potential raw materials for nutritional supplements. Another comment expresses concern that a soy isolate, from which natural vitamin E is derived, would not be considered a GRAS substance.

(Response) These comments seem to be concerned about the regulatory status of substances used as raw materials in the manufacture of a dietary ingredient or dietary supplement. An important consideration, however, is whether such materials become a component of the dietary ingredient or dietary supplement.

Dietary ingredient manufacturers who manufacture dietary ingredients for further processing by another person into a dietary supplement are outside the scope of this final rule. However, such manufacturers are still subject to other applicable statutory and regulatory provisions. For example, if you are a dietary ingredient manufacturer that uses a material in the manufacture of a dietary ingredient, and the material becomes part of the dietary ingredient, we would consider it to be part of the dietary ingredient and subject to the exception to the food additive definition in section 201(s)(6) of the act. However, because the material becomes a component of the dietary ingredient, you are subject to the applicable statutory and regulatory requirements that would apply to the dietary ingredient, including the safety of the dietary ingredient.

If you use a material, other than a dietary ingredient, in the manufacture of a dietary supplement, that becomes a

[10] Although we refer to the term ''food additive'' in the preamble, the reader should also consider color additives and substances prior-sanctioned for such use as being relevant to the discussion.

[11] It is important to note that it is the use of the substance, not the substance itself, that must be GRAS. The amount of a substance in the food is a critical factor in determining whether the use would be GRAS.

part of the dietary supplement, you are subject to the applicable statutory and regulatory requirements that apply to the use of such material, including its safety for such use. In this case, the use of the material would be subject to regulation as a food additive (unless it is GRAS or prior-sanctioned).

Alternatively, if you use material in the manufacture of a dietary ingredient or a dietary supplement that does not become part of the dietary ingredient or dietary supplement, then we would not consider the material to be a food.

(Comment 241) Several comments state the color additive provision would be too restrictive if it only allowed colors listed for use in a dietary supplement, rather than colors listed for use in foods generally. Some comments note none of the color additives currently approved generally for ''food'' use is approved specifically for dietary supplements within the food category. Another comment argues we gave no rationale for requiring a categorical listing under specific color additives for dietary supplements. The comment states color additives are not used in any greater amount in supplements than in foods and, if anything, are probably used less because supplements are consumed in smaller amounts than foods and less color additive must be used to achieve the desired effect. One comment notes it was not familiar with any evidence to indicate that a color additive (whether it is certified or exempt) found by us to be safe for use in foods is not safe in dietary supplements.

(Response) We acknowledge that the combination of proposed § 111.35(d)(3) and several color additive listings is confusing and could lead to incorrect conclusions about whether specific color additives may lawfully be used in a dietary supplement. As the comments point out, some listings for color additives (such as for the certified colors FD&C Blue No. 1 (21 CFR 74.101) and FD&C Red No. 40 (21 CFR 74.340)) list the color additive ''for coloring foods (including dietary supplements) generally'' (i.e., the listings specifically identify dietary supplements as a food category in which the color additive may be used). In contrast, some listings for color additives (such as for annatto extract (21 CFR 73.30) and for beta-carotene (21 CFR 73.95)) list the color additive ''for coloring foods generally'' (i.e., without specifically identifying dietary supplements as a food category in which the color additive may be used). In general, the terms of either of these two kinds of listings (i.e., ''for coloring foods (including dietary supplements) generally'' and ''for coloring foods generally'') mean we saw no need for restriction of the use of the color additive when FDA approved the listing of that color additive. Thus, a color additive listed for use in food generally may be used in a dietary supplement.

Although most listings of color additives provide for the use of the color additive in food generally, some listings for color additives restrict the use of the color additive in terms of the food category in which it may be used. For example, under 21 CFR 73.125 sodium copper chlorophyllin may be safely used to color citrus-based dry beverage mixes in an amount not exceeding 0.2 percent in the dry mix, and the terms of this listing would not include the use in a dietary supplement. We list a color additive with restrictions such as these when for example, the person who submits a petition for us to approve the listing of a color additive only requests a specific use, or when the available data and information only support the safety of a limited consumption of the color additive.

2. Final § 111.155(a)

Final § 111.155(a) (proposed § 111.40(a)(1)) requires you to visually examine each immediate container or grouping of immediate containers in a shipment you receive for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the components. Final § 111.155(a) is substantially similar to proposed § 111.40(a)(1) which would require you, for components you receive, to visually examine each container or grouping of containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition has resulted in contamination or deterioration of the components. Because you do not receive shipments for components you make, we are revising proposed § 111.40(a) so that it applies only to shipments of components you receive. We have added the word ''immediate'' to identify the container as the one in contact with the dietary supplement or component. We also have changed ''has resulted'' to ''may have resulted'' since in some cases you may not be able to make a final determination from a visual inspection alone whether the container condition has resulted in contamination or deterioration of the components.

(Comment 242) One comment supports the proposed requirements of proposed § 111.40(a) as an effective guideline for the inspection of purchased ingredients.

(Response) The provisions of final § 111.155(a) are requirements, not guidelines, as stated by the comment.

3. Final § 111.155(b)

Final § 111.155(b) (proposed § 111.40(a)(2)) requires you to visually examine the supplier's invoice, guarantee, or certification in a shipment you receive to ensure that the components are consistent with your purchase order. Final § 111.155(b) is substantially similar to proposed § 111.40(a)(2) which would require you to visually examine the supplier's invoice, guarantee, or certification to ensure the components are consistent with your purchase order and perform testing, as needed, to determine whether specifications are met. As with final § 111.155(a), final § 111.155(b) clarifies that the invoice, guarantee, or certification comes in the shipment you receive.

Final § 111.155(b) does not include any requirements related to testing components. Final § 111.75(a) sets forth the requirements to test or examine components; final §§ 111.110 and 111.120 set forth requirements for quality control personnel to ensure that appropriate tests or examinations are conducted, review the results of any tests or examination, determine whether components conform to specifications, and approve the components before they are used in the manufacture of a dietary supplement. Given this set of requirements, it would be redundant to set forth requirements regarding testing for components in final subpart G.

We did not receive comments specific to the requirements of proposed § 111.40(a)(2).

4. Final § 111.155(c)

Final § 111.155(c) (proposed § 111.40(a)(3)) requires you to quarantine components before you use them in the manufacture of a dietary supplement until:

- You collect representative samples of each unique lot of components (and, for components that you receive, of each unique shipment, and of each unique lot within each unique shipment);
- Quality control personnel review and approve the results of any test or examinations conducted on components; and
- Quality control personnel approve the components for use in the manufacture of a dietary supplement, including approval of any treatment (including in-process adjustments) of components to make them suitable for use in the manufacture of a dietary supplement, and release them from quarantine.

Final § 111.155 modifies proposed § 111.40(a)(3) which would require:

- You to quarantine components until your quality control unit reviews the supplier's invoice, guarantee, or certification;
- The quality control unit to perform testing, as needed, of a representative sample to determine that specifications are met;
- You to conduct a material review and make a disposition decision if specifications are not met; and
- The quality control unit to approve and release the components from quarantine before you use them.

Final § 111.155(c) includes revisions related to the following changes to other provisions already discussed.

- Under final § 111.110, quality control personnel ensure that all appropriate tests and examinations are conducted, and review and approve the results of tests and examinations conducted on components, but quality control personnel are not required to conduct the tests or examinations;
- Under final § 111.80(a), we establish the convention in this final rule of referring to ''each unique lot within each unique shipment'' rather than ''each shipment lot;''
- The requirements to conduct a material review and make a disposition decision are already set forth in final §§ 111.87, 111.113, and 111.120 and, therefore, are not repeated in final § 111.155; and
- Under final § 111.90(c), any batch of dietary supplement that is reprocessed, that contains components that you have treated, or to which you have made in-process adjustments to make them suitable for use in the manufacture of the dietary supplement, must meet all product specifications for the dietary supplement and be approved by quality control personnel before being released for distribution.

(Comment 243) Some comments address the requirement to quarantine components before you use them and assert that it is not feasible to quarantine incoming materials in a continuous extraction and purification operation, such as one built adjacent to a soy crushing or vegetable oil refinery to receive a continuous side stream flow from that operation. One comment explains that in such operations, quarantine and quality control approval occurs later in the process after the material has been isolated and concentrated in a stable matrix suitable for holding. One comment suggests proposed § 111.40(a)(3) state ''quarantine components or dietary supplements as applicable * * *''.

(Response) We decline to revise proposed § 111.40(a)(3) as suggested by the comments. The comment describes a situation where a manufacturer of a dietary supplement is also manufacturing a dietary ingredient or other component but only provides limited information. It appears that, however, the procedures described for quarantine of the isolated, stable matrix, with subsequent evaluation by quality control personnel before release for use in the manufacture of the dietary supplement, would satisfy the requirements of final § 111.155(c), provided quality control personnel are able to determine that all specifications for the component are met.

(Comment 244) One comment states that plant personnel who are not formally part of the manufacturer's quality control unit can conduct the quality control functions required for the release of materials from quarantine before use.

(Response) As already discussed with respect to the definition of quality control personnel (see section VI of this document), these comments may have misunderstood the role of the quality control unit (now quality control personnel). To clarify that role, final § 111.12(b) states you must identify a qualified person who is responsible for your quality control operations.

(Comment 245) One comment suggests components that cannot be used in a short time should be retested at least yearly.

(Response) We are making no changes to the provision after considering this comment. Whether any tests or examinations must be repeated over time, or whether the information in a certificate of analysis remains valid over time, is a matter to be decided by the manufacturer based on the established characteristics and shelf life of the component.

5. Final § 111.155(d)

Final § 111.155(d)(1) (proposed § 111.40(a)(4)) requires you to identify each unique lot within each unique shipment of components you receive and any lot of components that you produce in a manner that allows you to trace the lot to the supplier, the date received, the name of the component, the status of the component (e.g., quarantined, approved, or rejected), and to the dietary supplement you manufactured and distributed. Final § 111.155(d)(2) requires you to use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of components that you receive and any lot of components that you produce.

Final § 111.155(d)(1) and (d)(2) are substantially similar to proposed § 111.40(a)(4) which would require you to identify each lot of components in a shipment in a manner that allows you to trace the shipment to the supplier, the date received, the name of the component, and the status (e.g., quarantined, approved, or rejected), and to trace the shipment lot to the dietary supplement you manufactured and distributed. Proposed § 111.40(a)(4) also would require you to use this unique identifier whenever you record the disposition of each shipment lot received.

Final § 111.155(d)(1) and (d)(2) include revisions associated with final § 111.80(a).

We did not receive comments specific to proposed § 111.40(a)(4).

6. Final § 111.155(e)

Final § 111.155(e) (proposed § 111.40(a)(5)) requires you to hold components under conditions that will protect against contamination and deterioration and avoid mixups.

We did not receive comments specific to proposed § 111.40(a)(5).

F. What Requirements Apply to Packaging and Labels Received? (Final § 111.160)

1. Final § 111.160(a)

Final § 111.160(a) (proposed § 111.40(b)(1)) requires you to visually examine each immediate container or grouping of immediate containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the packaging and labels. Final § 111.160(a) is similar to proposed § 111.40(b)(1) with the addition of the word ''immediate'' to identify the container as the container that is in contact with the packaging or labels and substituting ''may have'' for ''has'' before the word ''resulted'' as discussed in this section.

We did not receive comments specific to proposed § 111.40(b)(1).

2. Final § 111.160(b)

Final § 111.160(b) requires you to visually examine the supplier's invoice, guarantee, or certification in a shipment to ensure the packaging or labels are consistent with your purchase order. Final § 111.160(b) is a new requirement that is analogous to proposed § 111.40(a)(2). We are requiring in final § 111.160(b), that, as part of your visual identification, you compare what was received, based on the supplier's invoice, guarantee, or certification, with

your purchase order so you can ensure your specifications for packaging and labels are met. This is consistent with what you would do with respect to components and dietary supplements you receive. Without final § 111.160(b), the review by quality control personnel under final § 111.120(a) would be a matter of performing receiving operations rather than performing quality control operations; as already discussed in this section, some comments asserted the quality control unit should focus on reviewing the work of others rather than conducting the operations themselves. Thus, final § 111.160 is consistent with these comments.

3. Final § 111.160(c)

Final § 111.160(c) requires you to quarantine packaging and labels before you use them in the manufacture of a dietary supplement until:

- You collect representative samples of each unique shipment, and of each unique lot within each unique shipment, of packaging and labels and, at a minimum, conduct a visual identification of the immediate containers and closures;
- Quality control personnel review and approve the results of any tests or examinations conducted on the packaging and labels; and
- Quality control personnel approve the packaging and labels for use in the manufacture of a dietary supplement and release them from quarantine.

Final § 111.160(c) is similar to proposed § 111.40(b)(2) which would require that:

- You quarantine packaging and labels until your quality control unit tests or examines a representative sample to determine that specifications are met;
- You conduct at least a visual identification of the containers and closures;
- If specifications are not met, you conduct a material review and make a disposition decision; and
- Your quality control unit approve and release packaging and labels from quarantine before you use them.

Final § 111.160(c) includes revisions that reflect the following change already discussed in this final rule:

- Refers to ''each unique lot within each unique shipment'' rather than ''each shipment lot''.

We did not receive comments specific to proposed § 111.40(b)(2).

4. Final § 111.160(d)

Final § 111.160(d)(1) requires you to identify each unique lot within each unique shipment of packaging and labels in a manner that allows you to trace the lot to the supplier, the date received, the name of the packaging and label, the status of the packaging and label (e.g., quarantined, approved, or rejected), and to the dietary supplement you distributed. Final § 111.160(d)(2) requires you to use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of packaging and labels. Final § 111.160(d) derives from proposed § 111.40(b)(3) which would require you to identify each shipment lot of packaging and labels in a manner that allows you to trace the shipment lot to the supplier, the date received, the name of the packaging and label and the status (e.g., quarantined, approved, or rejected) and to trace the shipment lot to the dietary supplement manufactured and distributed. Proposed § 111.40(b)(3) also would require that you use this unique identifier whenever you record the disposition of each shipment lot received.

Final § 111.160(d) includes revisions that reflect the following changes already discussed in this final rule:

- Reference to ''each unique lot within each unique shipment'' rather than ''each shipment lot.''
- As a clarification, final § 111.160(d)(2) refers to the ''dietary supplement that you distributed'' rather than to the ''dietary supplement manufactured and distributed'' to avoid a narrow—and incorrect—interpretation of ''manufactured.'' Under proposed § 111.40(b)(3), we used the term ''manufactured'' in a broad sense that includes any aspect of the manufacturing process rather than a narrow sense that applied to manufacturing operations for producing a batch of dietary supplement. Both proposed § 111.40(b)(3) and final § 111.160(e) address the need to trace the packaging and labels that you use to the product that you distribute, regardless of whether your role in the manufacturing process includes the production of the batch or includes only packaging a dietary supplement you receive from a supplier.

(Comment 246) One comment believes packaging and labels are rarely the source of quality problems. This comment suggests proposed § 111.40(b)(3) allow the use of packaging approved by the quality control unit without the need to use a specific lot identification number. The comment explains that this type of flexibility is needed when they have dozens of short run lots each day and use less than a carton of packaging supplies for each run.

(Response) This comment may have misinterpreted proposed § 111.40(b)(3). Under proposed § 111.40(b)(3) (final § 111.160(d)) you must assign the identifier to each unique lot within each unique shipment of packaging and labels when you receive them rather than each time that you use them. This number would stay the same for each of the short runs described by the comment. We are making no changes to the requirement.

5. Final § 111.160(e)

Final § 111.160(e) requires you to hold packaging and labels under conditions that will protect against contamination and deterioration, and avoid mixups. Final § 111.160(e) is identical to proposed § 111.40(b)(4).

We did not receive comments specific to proposed § 111.40(b)(4).

G. What Requirements Apply to a Product Received for Packaging or Labeling as a Dietary Supplement (and for distribution rather than for return to the supplier)? (Final § 111.165)

Final § 111.165 (proposed § 111.40(a)) sets out actions you must take when you receive a product for packaging and labeling and for distribution. Final § 111.165 includes editorial changes associated with the reorganization and revisions that reflect changes we are making to other sections of the final rule.

Final § 111.165 sets forth requirements for ''product that you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier)'' rather than for ''dietary supplements that you receive.''

The final rule separates the requirements in proposed § 111.40(a) for product that you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) (final § 111.165) from the analogous requirements for components, packaging, and labels (final § 111.155).

1. Final § 111.165(a)

Final § 111.165(a) requires you to visually examine each immediate container or grouping of immediate containers in a shipment of product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the received product. Final § 111.165(a) is substantially similar to proposed § 111.40(a)(1)

which, in part, would impose this requirement for dietary supplements you receive. We have added the word ''immediate'' to identify the container as the container that is in contact with the product you receive for packaging or labeling as a dietary supplement and substituted ''may have'' for ''has'' before the word ''resulted'' as explained in this section.

2. Final § 111.165(b)

Final § 111.165(b) requires you to visually examine the supplier's invoice, guarantee, or certification in a shipment of the received product to ensure the received product is consistent with your purchase order. Final § 111.165(b) is substantially similar to proposed § 111.40(a)(2) which, in part, would establish a similar requirement for dietary supplements that you receive.

3. Final § 111.165(c)

Final § 111.165(c) requires you to quarantine the received product until:

- You collect representative samples of each unique shipment, and of each unique lot within each unique shipment, of received product;
- Quality control personnel review and approve the documentation to determine whether the received product meets the specifications that you established under § 111.70(f); and
- Quality control personnel approve the received product for packaging or labeling as a dietary supplement and release the received product from quarantine.

Final § 111.165(c) is similar to proposed § 111.40(a)(3) which, in part, would require that:

- You quarantine dietary supplements that you receive until your quality control unit reviews the suppliers invoice, guarantee, or certification;
- The quality control unit performs testing, as needed, of a representative sample to determine that specifications are met;
- You conduct a material review and make a disposition decision if specifications are not met; and
- The quality control unit approves and releases the dietary supplements that you receive from quarantine before you use them.

Final § 111.165(c) includes revisions that reflect that under final § 111.75(e) before you package or label a product you received for packaging or labeling as a dietary supplement, you must visually examine the product and have documentation to determine whether the specifications you established under § 111.70(f) are met, but not otherwise examine or conduct tests.

4. Final § 111.165(d)

Final § 111.165(d)(1) requires that you identify each unique lot within each unique shipment of received product in a manner that allows you to trace the lot to the supplier, the date received, the name of the received product, the status of the received product (e.g., quarantined, approved, or rejected), and to the product you packaged or labeled and distributed as a dietary supplement. Final § 111.165(d)(2) requires you to use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of the received product. Final § 111.165(d) derives from proposed § 111.40(a)(4) which would require you, in part, to identify each lot of dietary supplements in a shipment in a manner that allows you to trace the shipment to the supplier, the date received, the name of the dietary supplement, and the status (e.g., quarantined, approved, or rejected), and to trace the shipment lot to the dietary supplement manufactured and distributed. Proposed § 111.40(a)(4) also would require you to use this identifier whenever you record the disposition of each shipment lot received.

Final § 111.165(d) includes a revision associated with final § 111.80 referring to ''each unique lot within each unique shipment'' rather than ''each shipment lot.''

5. Final § 111.165(e)

Final § 111.165(e) requires you to hold the received product under conditions that will protect against contamination and deterioration, and avoid mixups. Final § 111.165(e) derives from proposed § 111.40(a)(5) with editorial changes associated with the reorganization.

H. What Requirements Apply to Rejected Components, Packaging, and Labels, and to Rejected Products That Are Received for Packaging or Labeling as a Dietary Supplement? (Final § 111.170)

Final § 111.170 requires you to clearly identify, hold, and control under a quarantine system for appropriate disposition any component, packaging, and label, and any product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), that is rejected and unsuitable for use in manufacturing, packaging, or labeling operations. Final § 111.170 is substantially similar to proposed § 111.74 which would require you to clearly identify, hold, and control under a quarantine system any component, dietary supplement, packaging, and label that is rejected and unsuitable for use in manufacturing, packaging, or labeling operations.

We did not receive comments specific to proposed § 111.74. Final § 111.170 includes revisions associated with the series of provisions that distinguish a product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) from a dietary supplement you manufacture.

I. Under This Subpart, What Records Must You Make and Keep? (Final § 111.180)

Final § 111.180 sets forth the requirements to make and keep records associated with components, packaging, labels, and product you receive for packaging and labeling as a dietary supplement. Final § 111.180 derives from proposed § 111.40(c).

1. Final § 111.180(a)

Final § 111.180(a) requires you to make and keep records required under subpart G in accordance with subpart P. Final § 111.180(a) derives from proposed § 111.40(c)(2), with editorial changes associated with the reorganization.

We did not receive comments specific to the requirements set forth in final § 111.180(a).

2. Final § 111.180(b)(1)

Final § 111.153 requires you to establish and follow written procedures to fulfill the requirements of subpart G. These written procedures are records. Therefore, final § 111.180(b)(1) requires you to make and keep a record of the written procedures for fulfilling the requirements of subpart G.

3. Final § 111.180(b)(2)

Final § 111.180(b)(2) requires you to make and keep receiving records (including records such as certificates of analysis, suppliers' invoices, and suppliers' guarantees) for components, packaging, and labels, and for products you receive for packaging or labeling as dietary supplements (and for distribution rather than for return to the supplier). Final § 111.180(b)(2) derives from proposed § 111.40(c)(2) with editorial changes associated with the reorganization. Final § 111.180(b)(2) also includes revisions associated with the series of provisions that distinguish a product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) from a dietary supplement you manufacture. Because the final rule provides that you may rely, under

certain circumstances, on a certificate of analysis to ensure that some component specifications are met (final § 111.75(a)(2)(ii)) and that you may rely, in part, on documentation to determine whether specifications for received products are met, we specifically identify a certificate of analysis and common forms of documentation as being ''receiving records'' for purposes of this rule.

(Comment 247) One comment on proposed § 111.40(c)(2) points out the recordkeeping requirements of any final rule will be a costly burden for a company that produces multiple ingredient products in several packaging configurations and will be much greater than the burden for a company that produces batches of single ingredient products in one packaging configuration.

(Response) We acknowledge that companies that produce multiple ingredient products in several packaging configurations will have more records to keep than companies that produce single ingredient products in one packaging configuration. However, these records are necessary to be able to determine the source of the component, packaging, and labels, so that if adulteration of the dietary supplement occurs, the records will show the source of the material so that its use can be stopped.

4. Final § 111.180(b)(3)

Final § 111.180(b)(3) requires you to make and keep documentation that the requirements of subpart G were met. Under final § 111.180(b)(3)(i), the person who performs the required activity must document, at the time of performance, that the required operation was performed. Under final § 111.180(b)(3)(ii), the documentation must include:

- The date that the components, packaging, labels, or products you receive for packaging or labeling as a dietary supplement were received;
- The initials of the person performing the required operation;
- The results of any tests or examinations conducted on components, packaging, or labels, and of any visual examination of product you receive for packaging or labeling as a dietary supplement; and
- Any material review and disposition decision conducted on components, packaging, labels, or products that you receive for packaging or labeling as a dietary supplement.

Final § 111.180(b)(3) differs from proposed § 111.40(c)(1)(i) through (c)(1)(iv), by referring to ''required operation'' rather than ''requirement.'' Additionally as a conforming revision associated with final § 111.75(a) which requires appropriate tests and examinations, final § 111.180(b)(3) requires you to include in the documentation the results of any examinations as well as tests. Final § 111.180(b)(3) also includes revisions associated with the series of changes that distinguish a product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) from a dietary supplement that you manufacture.

(Comment 248) A few comments note proposed § 111.40(c) requires the signature of the person performing the requirement, whereas other sections of the 2003 CGMP Proposal, such as proposed § 111.50(c)(2), only require the initials of the person performing the requirement. One comment requests the format for the requirement to document the person performing the step be made consistent throughout the regulations.

(Response) We agree that the identity of the person performing a requirement should be required throughout the final rule and that this can be accomplished through initials except for operations that are performed by quality control personnel. Therefore, we are revising the requirements so that a signature (and not initials) is required for any operation performed by quality control personnel (see final § 111.140). Because § 111.40(c)(1)(ii) is not a quality control operation, we also revised proposed § 111.40(c)(1)(ii) (final § 111.180(b)(3)) to require the initials, rather than the signature, of the person performing the required operation. Initials are required for other circumstances that do not involve quality control operations, including final § 111.180(b)(3). However, whenever this final rule requires initials, a signature is also acceptable, because a signature would achieve the goal of identifying the person who performed the requirement.

XIII. Comments on the Production and Process Control System: Requirements for the Master Manufacturing Record (Final Subpart H)

A. Organization of Final Subpart H

In the 2003 CGMP Proposal, the requirements for the master manufacturing record were set forth in proposed § 111.45. As shown in table 9 of this document, we are setting forth the requirements for the master manufacturing record in a distinct subpart (final Subpart H—Production and Process Control System: Requirements for the Master Manufacturing Record). Table 9 lists the sections in final subpart H and identifies the proposed provisions that form the basis for the final rule.

TABLE 9.—DERIVATION OF SECTIONS IN FINAL SUBPART H

Final Rule	2003 CGMP Proposal
§ 111.205 What is the requirement to establish a master manufacturing record?	§ 111.45(a)(1), (a)(2), and (d)
§ 111.210 What must the master manufacturing record include?	§ 111.45(b)

The requirements in final subpart H are set forth from the perspective of the manufacture of a batch of a dietary supplement. You must comply with all requirements that pertain to your activity. However, you must comply with the requirement to prepare and follow a ''master manufacturing record'' regardless of whether you manufacture a batch, or whether you package or label product you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier). If you are a packager or labeler, you only need to include those parts relevant to your process. For example, if you are a labeler, under final § 111.210(c) you would not need to include an accurate statement of the weight or measure of each component to be used because you would be starting from packages already filled.

B. Highlights of Changes to the Proposed Requirements for the Master Manufacturing Record

1. Revisions

The final rule:

- Includes revisions that reflect that the final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1;
- Includes revisions so the requirements for the master manufacturing record are consistent with final § 111.70(a) which requires you to establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record; and
- Includes a revision associated with final § 111.75(h), which provides for the use of either tests or examinations for complying with the requirements of part 111.

2. Changes Associated With the Reorganization

The proposed requirement (§ 111.45(c)) that the quality control unit approve each master manufacturing record and any modifications to a master manufacturing record is set forth as final § 111.123(a) in subpart F, rather than in final subpart H, with the changes we made to the definition of ''quality control unit'' to ''quality control personnel'' as explained in section VI of this document (subpart A).

3. Changes After Considering Comments

The final rule:

- Retains a requirement to state any intentional overage of a dietary ingredient but does not require an explanation for such an overage;
- Provides flexibility to include either a representative label, or a cross-reference to the physical location of the actual or representative label if an actual label is not provided; and
- Provides flexibility for what must be included in written instructions when operations are not conducted manually.

C. General Comments on Proposed § 111.45 (Final Subpart H)

1. Comments on Written Procedures

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section. As discussed in section IV of this document, we do not require you to establish and follow written procedures for preparing a master manufacturing record.

2. Comments That Support Proposed § 111.45

(Comment 249) A few comments support the proposed requirements for the master manufacturing record. One comment states that properly recorded quality control measures, such as the batch production and master manufacturing records, will aid manufacturers in producing dietary supplements in a consistent and uniform manner, as well as serve as tools to assess possible sources of contamination and flaws in the production process. Another comment asserts the master manufacturing and batch production records probably have the second greatest impact on overall product quality, surpassed only by the quality of the ''people'' manufacturing the product.

(Response) We agree the master manufacturing record requirements in the 2003 CGMP Proposal are important for reasons that include those expressed in the comments. Establishing a master manufacturing record will help to ensure the quality of the dietary supplement. The proposed requirements for the master manufacturing record have been codified as subpart H in this final rule.

D. What Is the Requirement to Establish a Master Manufacturing Record? (Final § 111.205)

Final § 111.205 (proposed § 111.45(a) and (d)) sets forth the requirement to prepare and follow a written master manufacturing record.

1. Final § 111.205(a)

Final § 111.205(a) requires you to prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch. Final § 111.205(a) is similar to proposed § 111.45(a) which would require you to prepare and follow a written master manufacturing record for each type of dietary supplement you manufacture and for each batch size to ensure uniformity from batch to batch.

(Comment 250) Some comments suggest the phrase ''to ensure uniformity from batch to batch'' be changed to ''to ensure that specifications are met from batch to batch.'' One comment states the term ''uniformity'' could be interpreted to mean that two batches would be exactly the same, down to the minutest detail. The comment expresses concern about how batches of herbal products will meet this standard of ''uniformity'' from batch to batch.

(Response) These comments may have misinterpreted the term ''uniformity'' as we used it in proposed § 111.45(a). Uniformity means that the specifications you establish for identity, purity, strength, and composition of the finished batch must be the same throughout a given batch, e.g., at the beginning, middle, and end of a production run. To emphasize this, we have revised the requirement so it is clear that the uniformity relates to ''the finished batch.'' Whether two batches must be exactly the same, down to the minutest level, would depend on the specifications the manufacturer establishes for the finished batch under final § 111.70(e). Although a finished batch must meet those specifications ''from batch to batch,'' it is up to the manufacturer to determine what those specifications will be. We are making no changes to the requirement.

(Comment 251) Some comments assert that the proposed requirement to prepare a separate record ''for each batch size'' is burdensome, particularly for smaller firms who specialize in custom blended products. These comments would revise the rule so the master manufacturing record includes a master formula with instructions for how to adjust the amount of ingredients to add depending on the batch size, with the actual amounts included in the applicable batch record.

(Response) We disagree with these comments. Requiring a separate master manufacturing record for each batch size will lessen the likelihood of mistakes that can happen when a formula is ''multiplied up'' or ''divided down,'' particularly in light of the requirement that quality control personnel review and approve each master manufacturing record (final § 111.123(a)). Moreover, it is not clear that the scenario described in the comments would lessen any burden, because a new ''formula,'' based on the master formula, would still need to be prepared for each batch.

In essence, these comments suggest shifting the burden from a requirement to prepare a master manufacturing record to a requirement to prepare a batch record. Under final § 111.123, quality control personnel review the master manufacturing record before that record is used, but review the batch record only after the batch is prepared. Shifting the requirement in the manner suggested by these comments would defeat the purpose of having quality control personnel review and approve each ''formula.'' We are not making the suggested changes to proposed § 111.45(a).

We are changing the word ''type'' to ''unique formulation'' to clarify that the requirement for a master manufacturing record applies to each different dietary supplement whether it is a different strength, includes any different ingredients, is a capsule or tablet, or includes minor variations.

2. Final § 111.205(b)(1)

Final § 111.205(b)(1) requires that the master manufacturing record identify specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.205(b)(1) derives from proposed § 111.45(a)(1). We received no comments specific to proposed

§ 111.45(a)(1). We revised this section to include changes that we made to § 111.70(a).

3. Final § 111.205(b)(2)

Final § 111.205(b)(2) requires that the master manufacturing record establish controls and procedures to ensure that each batch of dietary supplement you manufacture meets the specifications identified in accordance with § 111.205(b)(1). Final § 111.205(b)(2) derives from proposed § 111.45(a)(2) with grammatical changes and changes associated with the reorganization. We did not receive comments specific to proposed § 111.45(a)(2).

4. Final § 111.205(c)

Final § 111.205(c) requires you to make and keep master manufacturing records in accordance with subpart P. Final § 111.205(c) derives from proposed § 111.45(a) and (d), and clarifies that you must prepare and keep the master manufacturing records. We did not receive comments specific to proposed § 111.45(d), and comments relevant to § 111.45(a) are discussed in the response to comment 250.

E. What Must the Master Manufacturing Record Include? (Final § 111.210)

Final § 111.210 sets forth the requirements for what the master manufacturing record must include. Final § 111.210 derives from proposed § 111.45(b).

1. Final § 111.210(a)

Final § 111.210(a) requires that the master manufacturing record include the name of the dietary supplement to be manufactured and the strength, concentration, weight, or measure of each dietary ingredient for each batch size. Final § 111.210(a) derives from proposed § 111.45(b)(1).

(Comment 252) One comment supports listing the weight or measure for each ingredient but believes that including the strength and concentration is unnecessary. This comment also suggests that the identity of each ingredient can be controlled using a unique item number identifier, along with a brief description of the ingredient.

(Response) Proposed § 111.45(b)(1) would require the master manufacturing record to include strength, concentration, weight, or measure of each dietary ingredient for each batch size. We did not intend that all would be required. The purpose of this requirement is to ensure the correct dietary ingredient and amount are used in a given batch. To the extent that weight or measure best describes what that dietary ingredient is and how much is to be used in a given batch, the manufacturer could use weight or measure. To the extent that a manufacturer determines, for a particular dietary ingredient, strength, or concentration would best describe what is to be used in a given batch, the manufacturer could use those instead. We are giving firms the flexibility to use the measure that they determine best describes the amount of dietary ingredient to use in their batch. For example, assume you are manufacturing a million tablets of a vitamin C product in 250 mg tablets and the only other ingredients in your product are starch, microcrystalline cellulose, and dicalcium phosphate. Under proposed § 111.45(b)(1) (final § 111.210(a)) your master manufacturing record would state: ''Vitamin C 250 mg, 1,000,000 tablets.'' As another example, if you are manufacturing 100 liters of a liquid dietary supplement that provides tuna oil as a dietary ingredient, and the only other ingredients are alpha-tocopherols for use as an antioxidant, then your master manufacturing record would state: ''Tuna oil, 100 liters.''

The unique identifier comment states ''the identity of each dietary ingredient can be controlled instead with the use of a unique item identifier, along with a brief description of the ingredient.'' It is not clear what the comment meant by ''a brief description of the ingredient.'' If the ''brief description of the ingredient'' includes the identity, then it would comply with the final rule. Firms are free to use unique identifiers in addition to the identity. If, however, the comment means something other than identity, the comment fails to explain how the identity will be controlled to prevent manufacturing errors. In the absence of such an explanation, we have no basis to make the requested change.

Moreover, under final § 111.205(c) the master manufacturing record is a record you must make and keep in accordance with final § 111.610 in final subpart P. Under final § 111.610, the master manufacturing record must be available during the record retention period for inspection and copying by us when we request that you do so. A master manufacturing record that does not identify the dietary ingredient and the weight or measure of the dietary ingredient would not allow an FDA investigator to determine, for example, how your master manufacturing record relates to the finished dietary supplement and to the product label of that dietary supplement.

(Comment 253) One comment recommends the weight or measure be expressed per unit or portion, or per unit of weight or measure of the product, for each batch size.

(Response) The final rule does not prescribe the units you must use. Thus, firms have the flexibility to include this information in the way that best suits their product.

2. Final § 111.210(b)

Final § 111.210(b) requires that the master manufacturing record include a complete list of components to be used. Final § 111.210(b) is identical to proposed § 111.45(b)(2). We did not receive comments specific to proposed § 111.45(b)(2).

3. Final § 111.210(c)

Final § 111.210(c) requires that the master manufacturing record include an accurate statement of the weight or measure of each component to be used. Final § 111.210(c) is identical to proposed § 111.45(b)(3). We did not receive comments specific to proposed § 111.45(b)(3).

4. Final § 111.210(d)

Final § 111.210(d) requires that the master manufacturing record include the identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label and the identity of each ingredient that will be declared on the ingredients list of the dietary supplement. Final § 111.210(d) is similar to proposed § 111.45(b)(4). We have removed the phrase ''in compliance with section 403(s) of the act'' as it is unnecessary in the context of compliance with the dietary supplement CGMP requirements. The manufacturer must still comply with section 403(s) and failure to do so will result in a misbranding violation, not a CGMP violation under this final rule.

(Comment 254) One comment supports having the identity and weight or measure of each dietary ingredient as required by proposed § 111.45(b)(4), but asserts it is unnecessary for the verbiage to identically match the corresponding label statements. This comment also asserts that the ingredients can be controlled in the master manufacturing record by use of a unique identifier, instead of the ingredient name, along with a brief description of the ingredient.

(Response) We disagree for the reasons stated in response to comment 252 and decline to revise the provision in this manner.

5. Final § 111.210(e)

Final § 111.210(e) requires that the master manufacturing record include a statement of any intentional overage

amount of a dietary ingredient. Final § 111.210(e) derives from proposed § 111.45(b)(5) which would require you to explain any intentional excess amount of a dietary ingredient.

(Comment 255) Some comments request us to modify this requirement. Several comments note that a manufacturer may design products with overage levels adjusted so the product always tests at least 100 percent of the amount claimed on the label throughout the declared shelf life. One comment states it should be sufficient to identify any overage amount, rather than having to explain it.

(Response) We understand that some firms design products using an additional amount of certain ingredients to ensure the product meets its specifications for the amount of the ingredient during the expected shelf life of the product. We agree it is not necessary to include the reason for adding the intentional excess amount.

We also understand it would be more appropriate to refer to the additional amount as an ''overage'' amount rather than an ''excess'' amount, because ''overage'' is commonly used in the industry to convey the practice that is now the subject of final § 111.260(e). Therefore, we have revised proposed § 111.45(b)(1) to use the term ''overage'' rather than ''excess'' and to delete the proposed requirement to include the reason for the intended overage. As discussed in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12203), the amount of overage should be limited to the amount needed to meet the amounts listed in accordance with final § 111.210(d).

6. Final § 111.210(f)

Final § 111.210(f) requires that the master manufacturing record include a statement of theoretical yield of a manufactured dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to ensure the quality of the dietary supplement, and the expected yield when you finish manufacturing the dietary supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary and material review is conducted and disposition decision is made. Final § 111.210(f) derives from proposed § 111.45(b)(6). We revised the section to state ''beyond which a deviation investigation of a batch is necessary'' rather than ''beyond which a deviation is performed'' for clarity.

(Comment 256) One comment suggests the term ''maximum and minimum percentages'' in proposed § 111.45(b)(6) be replaced with the term ''normal range.''

Another comment recommends proposed § 111.45(b)(6) be replaced with: ''A statement of theoretical yield of a manufactured dietary ingredient or dietary supplement expected at appropriate phases of manufacturing.'' This comment states the detail in this proposed requirement should be eliminated because the manufacturer should decide where and when to include a statement about theoretical yield.

(Response) Final § 111.210(f) clearly communicates when it is necessary to conduct a material review and make a disposition decision. The comment's suggestions do not improve the communication or clarify this point.

Final § 111.210(f) gives firms the flexibility to decide what steps, in the manufacturing process, are points, steps, or stages where control is needed to ensure the quality of the dietary supplement. A statement about theoretical yield is necessary at each such point, step, or stage including at the finished batch stage so that you will know, when you manufacture a batch, whether the process is proceeding as expected or whether something is wrong. For example, your master manufacturing record could state the theoretical yield after mixing a series of components is 100 percent, because nothing about the additional step would remove any material from the production system. When manufacturing the batch, a yield of less than 100 percent would tell you something was wrong, for example, if there was an obstruction that prevented a component that was being delivered by automated equipment from actually entering the production vessel. For a process such as recrystallization, knowing the theoretical yield is critical, because if the expected yield is not achieved at a given step it may mean that the process did not proceed as intended.

(Comment 257) One comment argues it is not possible for the majority of supplement products, especially botanicals, to provide 100 percent of the claimed amount of the botanical, because botanicals are inherently of uneven consistency, density, and particle size. This comment recommends that we allow for variability in yield, especially for botanicals.

(Response) Final § 111.210(f) does not specify what the yield must be, so no revision is necessary. It is the manufacturer's responsibility to manufacture the product in a way that will ensure that a product contains what the manufacturer has established in its specifications and its master manufacturing record. The manufacturer must establish specifications for the identity, purity, strength, and composition and limits on contamination and other specifications the manufacturer decides are necessary to ensure the quality of the dietary supplements that it makes, and design and implement a production and process control system that will ensure those specifications are met. In the situation described by the comment, it is the manufacturer's responsibility to design and implement a production and process control system that will ensure the quality of the dietary supplement regardless of the problems presented by the nature of the ingredients.

7. Final § 111.210(g)

Final § 111.210(g) requires that the master manufacturing record include a description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label. Final § 111.210(g) derives from proposed § 111.45(b)(7), which would require a description of packaging and a copy of the label to be used.

(Comment 258) One comment supports the proposed requirement that the master manufacturing record contain a copy of the dietary supplement label. Other comments contend that the proposed requirement to include a copy of the label is neither appropriate nor necessary. Some comments state that companies often do not have a label available to include in the master manufacturing record and believe that a description of the packaging or label in the master manufacturing record should be sufficient. Another comment, by a company that produces many different brands for each bulk product, asserts that updating labels in the record would be burdensome and suggests wording similar to that used by USP, for which a positive identification of all labeling used is permitted. One comment asks whether the packaging and label copy requirements can be in separate documents cross-referenced in the master manufacturing record, because some companies treat tablet manufacturing and packaging as two separate and distinct operational elements. This comment explains that the master manufacturing record includes the specifics required to manufacture the tablets, but the actual description of packaging and label copy requirements are contained in separate documents cross-referenced to the

master manufacturing record by a product part number.

(Response) We understand there may be some circumstances where it would be impractical to have actual copies of labels in the master manufacturing record. If an actual label is not available, you may include a representative label in the master manufacturing record. A representative label could be a graphic representation of the label, including the exact statements that would be on the product label, or a detailed description of the statements and other information (such as pictures or graphics) that will be on the actual label. The representative label must be an accurate representation of the label that will be affixed to the dietary supplement distributed. We also agree that it would be acceptable to cross-reference the physical location of the actual or representative label.

Finally, because the actual or representative label is a record that you must make and keep in accordance with final § 111.610 in final subpart P, it must be readily available during the retention period for inspection or copying by FDA. Thus, we are revising proposed § 111.45(b)(6) (final § 111.210(g)) as discussed above.

(Comment 259) One comment states that a company that manufactures a dietary supplement under contract to another company would not have access to the product label.

(Response) Under final § 111.210(g) a company that manufactures a dietary supplement under contract could comply with the requirement by, for example, providing the name and address of the company who contracted for the manufacture of the batch as the cross-reference to the physical location of the label.

8. Final § 111.210(h)(1)

Final § 111.210(h)(1) requires that the master manufacturing record include written instructions for specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.210(h)(1) is similar to proposed § 111.45(b)(8)(i) which would require that the master manufacturing record include written instructions for specifications for each point, step, or stage in manufacturing the dietary supplement necessary to prevent adulteration. Final § 111.210(h)(1) includes changes that we are making for consistency with final § 111.70(a).

We did not receive comments specific to proposed § 111.45(b)(8)(i).

9. Final § 111.210(h)(2)

Final § 111.210(h)(2) requires that the master manufacturing record include written instructions for procedures for sampling, and a cross-reference to procedures for tests or examinations. Final § 111.210(h)(2) derives from proposed § 111.45(b)(8)(ii), which would require that the master manufacturing record include written instructions for sampling and testing.

(Comment 260) A few comments object to including certain written instructions for sampling and testing procedures in the master manufacturing record. One comment states that this documentation, such as laboratory testing procedures, would be a burdensome task and should be maintained separate from the master manufacturing record and be retrievable by appropriate cross-referencing information.

(Response) As we discussed in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12204), the written instructions are similar to a recipe. As such, the written instructions must include instructions related to procedures for sampling plans so you can collect appropriate samples for tests or examinations. We agree, however, that it is not necessary for the master manufacturing record to include written instructions for tests or examinations. Accordingly, we have revised the provision to permit the master manufacturing record to include a cross-reference to the procedures for tests or examinations. The final rule includes a requirement that you establish and follow written procedures for laboratory operations, including for tests and examinations that you conduct to determine whether specifications are met (final § 111.303). In essence, these written procedures for tests and examinations would constitute the written instructions that we proposed under § 111.45(b)(8)(ii) for testing procedures. This requirement for written procedures is generally described in section IV of this document.

10. Final § 111.210(h)(3)

Final § 111.210(h)(3) requires that the master manufacturing record include written instructions for specific actions necessary to perform and verify each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.210(h)(3) derives from proposed § 111.45(b)(8)(iii) which would require that the master manufacturing record include written instructions for specific actions necessary to perform and verify each point, step, or stage necessary to meet specifications and otherwise prevent adulteration. Final § 111.210(h)(3) includes changes for consistency with final § 111.70(a).

Final § 111.210(h)(3)(i) requires that the specific actions include verifying the weight or measure of any component and verifying the addition of any component. Final § 111.210(h)(3)(ii) requires that, for manual operations, the specific actions include: (1) One person weighing or measuring a component and another person verifying the weight or measure and (2) one person adding a component and another person verifying the addition. Final § 111.210(h)(3)(i) and (h)(3)(ii) derive from proposed § 111.45(b)(8))(iii).

(Comment 261) Some comments suggest the requirement to have more than one person involved in performing and verifying each point, step, or stage in the manufacturing process is overly prescriptive and that alternative, reliable methods for verifying the weighing and addition of components should be permitted. One comment explains many manufacturers use bar code systems to identify the weight and identity of components both before and after weighing. In such cases, a computer generated weight record and corresponding bar code can be created and affixed to the container by one individual as reliable verification of the material's contents and weight. Likewise, the addition of components to a blender can be adequately controlled and verified by one person through scanning technology that allows reliable verification of the identity and weight of components added to a blender without the need for a second person.

(Response) These comments describe a system partially under the control of automated equipment. Final § 111.30 establishes a series of requirements for automated equipment. We agree that, with such requirements in place for an automated system such as that described by the comments, the requirement to verify the weight or measure of a component, or to verify the addition of a component, can be achieved without requiring that one person do the weighing or measuring and another person verify the weighing or measuring and without requiring that one person add the component and another person verify the addition. Therefore, final § 111.210(h)(3) provides both that the written instructions must

include verifying the weight or measure of any component and verifying the addition of any component and that, for manual operations, the written instructions must include: (1) One person weighing or measuring a component and another person verifying the weight or measure and (2) one person adding a component and another person verifying the addition. The final rule makes clear that there must be a verification step and gives firms flexibility, when the weighing or addition is not done manually, to determine how they would accomplish the verification.

11. Final § 111.210(h)(4)

Final § 111.210(h)(4) requires that the master manufacturing record include written instructions for special notations and precautions to be followed. Final § 111.210(h)(4) derives from proposed § 111.45(b)(8)(iv). We did not receive comments specific to proposed § 111.45(b)(8)(iv).

12. Final § 111.210(h)(5)

Final § 111.210(h)(5) requires that the master manufacturing record include written instructions for corrective action plans for use when a specification is not met. Final § 111.210(h)(5) derives from proposed § 111.45(b)(8)(v).

(Comment 262) Several comments argue pre-established corrective action plans are not useful for complex failure scenarios, and that the quality control unit should instead approve corrective action procedures on a case-by-case basis. One comment suggests the rule should refer to ''procedures'' rather than specifying ''corrective action plans.''

(Response) We acknowledge that corrective action plans would be focused on each point, step, or stage where control is necessary to ensure the quality of the dietary supplement. We also acknowledge that it may not be practical to establish a corrective action plan for all foreseeable circumstances. In circumstances such as the complex failure scenario described by the comments, the documentation of the material review and disposition decision (rather than the corrective action plan) would identify the action taken to correct, and prevent a recurrence of, the deviation and discuss what you did with the batch (final § 111.140(b)(3)(iv) and (b)(3)(v)). However, we disagree that the fact that it may not be practical to establish a corrective action plan for all foreseeable circumstances means you could not establish a corrective action plan at each point, step, or stage where you can, in fact, predict a scenario and provide a plan for action when that scenario presents itself. Therefore, for any circumstance you can predict, final § 111.210(h)(5) requires that you establish corrective action plan.

F. Quality Control Responsibility (Proposed § 111.45(c))

In proposed § 111.45(c) we would require the quality control unit to review and approve each master manufacturing record and any modifications to a master manufacturing record. As part of the reorganization, this requirement is set forth under final § 111.123(a) in subpart F for quality control personnel. There is no reason to repeat the requirement in final subpart H and, thus, it does not appear in final subpart H.

XIV. Comments on the Production and Process Control System: Requirements for the Batch Production Record (Final Subpart I)

A. Organization of Final Subpart I

In the 2003 CGMP Proposal, the proposed requirements for the batch production record were set forth in § 111.50. As shown in table 10 of this document, we are setting forth the requirements for the batch production record in a distinct subpart (final Subpart I—Production and Process Control System: Requirements for the Batch Production Record) that contains the requirements that derive from proposed § 111.50. In addition, we are moving some proposed requirements from §§ 111.35 and 111.37 into final subpart I. Table 10 lists the sections in final subpart I and identifies the provisions that form the basis for the final rule.

TABLE 10.—DERIVATION OF SECTIONS IN FINAL SUBPART I

Final Rule	2003 CGMP Proposal
§ 111.255 What is the requirement to establish a batch production record?	§ 111.50(a), (b), and (i)
§ 111.260 What must the batch record include?	§ 111.35(i)(2), (j), (m), and (o)(2) § 111.37(b)(3), (b)(5), and (b)(9) § 111.50(c)(1) through (c)(11), (c)(13), (c)(14), (d)(2), (e), and (g) § 111.70(b)(6), (e), and (g)

The requirements in final subpart I are set forth from the perspective of the manufacture of a batch of a dietary supplement. However, you must comply with the requirement to prepare and follow a ''batch production record'' or a ''batch record'' regardless of whether you manufacture a batch or whether you package or label product you receive from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier). As discussed in section VI of this document, if you are a packager or labeler, you only need to include those parts relevant to your process. For example, if you are a labeler under final § 111.260(e) you would not need to include the identity and weight or measure of each component used, because you would be starting from packages that already had been filled.

B. Highlights of Changes to the Proposed Requirements for the Batch Production Record

1. Revisions

The final rule:

- Includes revisions that reflect that the final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.
- Does not use the term ''shipment lot'' when referring to components.

2. Changes Associated With the Reorganization

- Several provisions derive in whole or in part from proposed §§ 111.35, 111.37, or 111.70.
- Several requirements in proposed § 111.50 are redundant to requirements set forth in other subparts and are not repeated in subpart I.
- Several proposed requirements for reprocessing are moved to final § 111.90 in final subpart E.
- The proposed requirement to collect reserve samples of each batch of dietary supplement is moved to final § 111.83 in subpart E, where we clarify that the requirement relates to each lot of packaged and labeled dietary supplement rather than to a finished batch awaiting packaging and labeling.

3. Changes After Considering Comments

The final rule:

- Provides flexibility for firms to document information about the maintenance, cleaning, and sanitizing of equipment used in producing the batch in either the batch production record or in individual equipment logs that it cross-references in the batch production record.
- Provides flexibility for firms to include in the batch production record

either the results of any testing or examination performed, or a cross-reference to the results of any testing or examination.

C. What Is the Requirement to Establish a Batch Production Record? (Final § 111.255)

Final § 111.255(a) requires you to prepare a batch production record every time you manufacture a batch of a dietary supplement. Final § 111.255(b) requires that the batch production record include complete information relating to the production and control of each batch. Final § 111.255(a) and (b) derive from proposed § 111.50(a), with a nonsubstantive revision that divides the proposed requirements into two separate paragraphs.

Final § 111.255(c) requires your batch production record to accurately follow the appropriate master manufacturing record and you to perform each step in the production of the batch. Final § 111.255(c) derives from proposed §111.50(b).

Final § 111.255(d) requires you to make and keep batch production records in accordance with subpart P. Final § 111.255(d) derives from proposed § 111.50(i) with editorial changes associated with the reorganization.

We did not receive comments specific to proposed § 111.50(a), (b), or (i).

D. What Must the Batch Record Include? (Final § 111.260)

1. Final § 111.260(a)

Final § 111.260(a) requires the batch production record to include the batch, lot, or control number: (1) Of the finished batch of dietary supplement and (2) that you assign in accordance with § 111.415(f) for each lot of packaged and labeled dietary supplement from the finished batch of dietary supplement, and for each lot of dietary supplement, from the finished batch of dietary supplement, that you distribute to another person for packaging or labeling.

Final § 111.260(a) derives, in part, from proposed § 111.50(c)(1), which would require the batch, lot, or control number in the batch production record. Consistent with comments that requested that we clarify responsibilities when more than one party is involved with the manufacturing, packaging, labeling, or holding of a dietary supplement (see section VI of this document), we have added the requirements of final § 111.260(a)(1), (a)(2)(i), and (a)(2)(ii) to ensure that you are able to determine the manufacturing history and control of the packaged and labeled dietary supplement from all stages of manufacturing through distribution, and to be consistent with other provisions of this final rule. In the discussion of subpart L (section XVII of this document), we explain in detail final § 111.410(d), which requires you to be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution. In that same section, we explain final § 111.415(f) which requires you to assign a batch, lot, or control number to each lot of packaged and labeled dietary supplement from a finished batch and each lot of dietary supplement from a finished batch that you distribute to another person for packaging and labeling. In that way, these batch, lot, or control numbers can be used to determine the manufacturing history and control of the batch. However, you can determine how you track the batch, lot, or control number of the packaged and labeled dietary supplement, or dietary supplement you send to another person for packaging and labeling, to a distributed dietary supplement.

We did not receive comments specific to proposed § 111.50(c)(1). We respond to comments relevant to final subpart L in section XVII of this document.

2. Final § 111.260(b)

Final § 111.260(b) requires that the batch production record include the identity of equipment and processing lines used in producing the batch and derives from proposed § 111.50(c)(3).

We did not receive comments specific to proposed § 111.50(c)(3).

3. Final § 111.260(c)

Final § 111.260(c) requires that the batch production record include the date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained. Final § 111.260(c) derives from proposed § 111.50(c)(4).

(Comment 263) Many comments argue that it is not necessary or appropriate to retain the records of maintenance, cleaning, and sanitizing equipment and processing lines in the batch production record. These comments request that the final rule provide flexibility to retain such records in individual equipment files or log books for easy access. One comment recommends the requirement to retain such records be set forth within subpart D.

(Response) As discussed in section IX of this document (final § 111.35(b)(2)), we agree with these comments. Consistent with final § 111.35(b)(2), final § 111.260(c) provides flexibility to retain the records of maintenance, cleaning, and sanitizing equipment and processing lines in either the batch production record or another record you cross-reference in the batch production record.

4. Final § 111.260(d)

Final § 111.260(d) requires that the batch production record include the unique identifier you assigned to each component (or, when applicable, to a product you receive from a supplier for packaging or labeling as a dietary supplement), packaging, and label used. Final § 111.260(d) derives from proposed § 111.50(c)(5), which would require that the batch record include the shipment lot unique identifier of each component, dietary supplement, packaging, and label used. Consistent with the convention we are establishing under final §§ 111.80(a), 111.155, and 111.160, final § 111.260(d) does not use the term ''shipment lot.''

We did not receive comments specific to proposed § 111.50(c)(5).

5. Final § 111.260(e) and (f)

Final § 111.260(e) requires that the batch production record include the identity and weight or measure of each component used and derives from proposed § 111.50(c)(6).

Final § 111.260(f) requires that the batch record include a statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing. Final § 111.260(f) derives from proposed § 111.50(c)(9).

(Comment 264) A few comments argue that the requirements in proposed § 111.50(c)(6) are not applicable to continuous operations and that yield information required in proposed § 111.50(c)(9) is irrelevant for quality control in continuous operations used for producing dietary ingredients. One of these comments also discusses ''continuous operations,'' such as a continuous operation built adjacent to a soy crushing or vegetable oil refinery to receive a continuous side stream flow from that operation (see the discussion of final § 111.155(c) in section XII of this document). This comment explains that in such operations, quarantine and quality control approval occurs after the material has been isolated and concentrated in a stable matrix suitable for holding.

(Response) Based on the limited information provided by these comments, it appears that they are describing the manufacture of a ''dietary

ingredient'' or other component that will subsequently be used in the manufacture of a dietary supplement. Therefore, in this scenario, the identity and weight or measure of the stable matrix must be taken. The statement of the actual yield and the theoretical yield refers to the batch in which the stable matrix is added as a component.

6. Final § 111.260(g)

Final § 111.260(g) requires that the batch production record include the actual results obtained during any monitoring operation. Final § 111.260(g) derives from proposed § 111.35(o)(2) which would require you to make and retain records of the actual results obtained during monitoring of the in-process production. Consistent with the reorganization we are specifying that the records of monitoring be located in the batch production record, because the monitoring is associated with the batch production.

We did not receive comments specific to proposed § 111.35(o)(2).

7. Final § 111.260(h)

Final § 111.260(h) requires that the batch production record include the results of any testing or examination performed during the batch production, or a cross-reference to such results. Final § 111.260(h) derives from proposed § 111.50(c)(10) which would require you to record the actual results of any testing performed during production of the batch.

(Comment 265) A few comments object to the requirement in proposed § 111.50(c)(10) that actual test results be included in the batch production record. These comments state test results are typically retained in other records, such as laboratory records, and that it would be duplicative to include such results in the batch production record. One comment states the ''actual'' (original record of) test results may not be available to the manufacturer when the testing is performed electronically or an outside laboratory does the testing. This comment adds for test results obtained in-house, original records are typically kept as part of the master laboratory records and cross-referenced in batch records.

(Response) After considering these comments, we are providing flexibility to either include the results of tests or examinations in the batch production record, or provide a cross-reference to such results. We note that final § 111.260(h) does not require that you have the original documentation of the test results. If an outside laboratory has performed testing for you, you must obtain a copy of the test results and include these in your batch production record or in another appropriate record that you can cross-reference and make readily available for inspection.

8. Final § 111.260(i)

Final § 111.260(i) requires that the batch production record include documentation that the finished dietary supplement meets specifications established in accordance with § 111.70(e) and (g). Final § 111.260(i) derives from proposed § 111.50(c)(11). We have made a change to identify which required specifications the dietary supplement must meet.

We did not receive comments specific to proposed § 111.50(c)(11).

9. Final § 111.260(j)

Final § 111.260(j) sets forth the requirements for documentation you must make and include in the batch production record, at the time of performance, of the manufacture of the batch. Final § 111.260(j) derives from proposed § 111.50(c)(2) and (c)(7).

a. *Final §111.260(j)(1)*. Final § 111.260(j)(1) requires documentation, at the time of performance, of the date on which each step of the master manufacturing record was performed. Final §111.260(j)(1) derives from proposed § 111.50(c)(2). We did not receive comments specific to proposed § 111.50(c)(2).

b. *Final §111.260(j)(2)*. Final § 111.260(j)(2) requires documentation, at the time of performance, of the initials of the persons performing each step in the master manufacturing record. Final § 111.260(j)(2) derives from the second part of proposed § 111.50(c)(2),(c)(7) and (c)(8).

(Comment 266) One comment asks whether the persons responsible for batch production must be identified by name or by position.

(Response) The requirement is for the initials of the name of the person rather than for identification of the position. Requiring that the record include the initials of the person(s) performing each step in the master manufacturing record means that the person performing the step is the person who physically initials the batch record at the time the person performs the step. The intent is for the person to acknowledge that he or she performed the requirement rather than to merely provide information that would identify that person.

(Comment 267) One comment asks whether we will allow electronic signatures for batch production records, laboratory test results, and quality control unit documentation. The comment notes that many companies have fully computerized, automated production and quality control management systems that utilize password-protected (or otherwise secure) means of entering data at key quality control steps.

(Response) The use of electronic signatures is governed by our regulations in part 11, which control whether electronic signatures are permitted. Our guidance entitled ''Guidance for Industry Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' available at *http://www.fda.gov/cder/guidance/5667fnl.htm*, discusses the use of electronic signatures (Ref. 33).

c. *Final § 111.260(j)(2)(i) through § 111.260(j)(2)(iv)*. Final § 111.260(j)(2)(i) requires you to document at the time of performance the initials of the person responsible for weighing or measuring each component used in the batch, and final § 111.260(j)(2)(ii) requires you to document at the time of performance the initials of the person responsible for verifying the weight or measure of each component used in the batch. Final § 111.260(j)(2)(i) and (j)(2)(ii) derive from proposed § 111.50(c)(2)(i) and (c)(7), respectively.

Final § 111.260(j)(2)(iii) requires you to document, at the time of performance, the initials of the person responsible for adding the component to the batch; and final § 111.260(j)(2)(iv) requires you to document, at the time of performance, the initials of the person responsible for verifying the addition of components to the batch. Final § 111.260(j)(2)(iii) derives from proposed § 111.50(c)(2)(ii) and final § 111.260(j)(2)(iv) derives from proposed § 111.50(c)(8).

We did not receive comments specific to proposed § 111.50(c)(2)(i) and (c)(2)(ii) or § 111.50(c)(7) and (c)(8).

10. Final § 111.260(k)

Final § 111.260(k) sets forth the requirements for documentation you must make and include in the batch production record, at the time of performance, of the packaging and labeling operations. Final § 111.260(k) derives from proposed § 111.70(g) which we discuss in the following paragraphs.

In final § 111.260(k)(3), we are eliminating proposed § 111.70(g)(4) which would require that the documentation include any material reviews and disposition decisions for packaging and labels, because it would be redundant to final § 111.180(b)(4)(ii)(D).

a. *General comments on proposed § 111.70(g)*.

(Comment 268) Some comments assert that the requirement of proposed § 111.70(g) that all packaging releases be placed in the batch production record is unnecessary. According to the comments, most packaging material lots are used in multiple batches. The comments assert that a requirement for this disposition information to be copied into each batch production record is unnecessary as long as lot traceability exists and this information is kept in a central file.

(Response) These comments may have misinterpreted proposed § 111.70(g). It would require that the documentation in the batch production record for packaging and label operations include: (1) The identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use, (2) the examination conducted in accordance with proposed § 111.70(b)(7), (3) the conclusions reached from retests conducted in accordance with proposed § 111.70(e), and (4) any material reviews and disposition decisions for packaging and labels. None of these proposed requirements would require that ''packaging releases'' be included in the batch record.

The requirements for documentation for packaging you receive are set forth in final § 111.180(b) in subpart G.

b. *Final § 111.260(k)(1).* Final § 111.260(k)(1) requires the documentation of packaging and labeling operations to include the unique identifier you assigned to packaging and labels used, the quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels. Final § 111.260(k)(1) derives from proposed § 111.70(g)(1) which would require that the documentation include the identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use. For consistency with other provisions of this final rule, such as final § 111.160(e)(1), final § 111.260(k)(1) requires ''the unique identifier you assigned to packaging and labels used,'' rather than ''the identity of packaging and labels used.'' Final § 111.260(k)(1) also includes changes we are making after considering comments.

(Comment 269) Some comments assert comprehensive label reconciliation should not be required if appropriate electronic controls are instituted to ensure that correct labels are used during labeling operations. The comments state this alternative is permitted for labeling operations for drug products, which are generally identical or similar in nature to labeling operations for dietary supplements. As such, the comments assert the same flexibility should be afforded to dietary supplement manufacturers. Some comments specifically suggest changing the language of proposed § 111.70(g)(1) to read ''The identity and quantity of the packaging and labels used and either reconciliation of any discrepancies between issuance and use or use of appropriate electronic or electromechanical equipment to conduct a 100-percent examination for labeling during or after completion of finishing operations.''

(Response) We agree that label reconciliation need not be required for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations. Thus we have made two changes in this final rule in addition to the changes in final § 111.260(k)(1) that provide there must be label reconciliation when such reconciliation is required either to account for discrepancies or to ensure the use of the label that is specified in the master manufacturing record. First, we have revised the final rule in subpart L (for packaging and labeling operations) to provide that you need not conduct label reconciliation if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations (see discussion of final § 111.410(b) in subpart L in section XVI of this document). Second, final § 111.260(k)(1), requires you to include documentation in the batch production of reconciliation of any discrepancies between issuance and use of labels only when label reconciliation is required.

c. *Final § 111.260(k)(2).* Final § 111.260(k)(2) requires the documentation of packaging and labeling operations to include an actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record. Final § 111.260(k)(2) derives from proposed § 111.50(c)(12) which would require that the batch production record include copies of all container labels used and the results of examinations conducted during the label operation to ensure that the containers have the correct label.

(Comment 270) A few comments ask that we clarify the container labels that proposed § 111.50(c)(12) is referring to. Specifically, these comments ask whether proposed § 111.50(c)(12) is referring to finished product labels, bulk material labels, or in-process container labels. One comment asserts proposed § 111.50(c)(12) is unnecessary for ensuring the dosage form of dietary supplements meets specifications.

One comment finds proposed § 111.50(c)(12) confusing, because it does not specify what is meant by ''label operation.'' This comment notes that during the course of manufacturing operations, containers holding in-process materials are often labeled but the comment assumes that proposed § 111.50(c)(12) does not require the retention of copies of in-process container labels, which would not add significant value toward the assurance of a quality product.

In general, these comments ask for clarification of proposed § 111.50(c)(12), and suggest it be deleted.

(Response) Proposed § 111.50(c)(12) referred to the product label that would be affixed to the containers that hold the packaged and labeled dietary supplement. We did not receive any comments that a related requirement (in proposed § 111.45(b)(7) in the master manufacturing record) was confusing or needed clarification. We therefore believe that the requirement that the batch production record include a label will be clearer if we state the requirement in a way that is similar to the requirement in proposed § 111.45(b)(7). However, because comments to proposed § 111.45(b)(7) persuaded us to provide flexibility for (1) having a representative label rather than an actual label and (2) cross-referencing the physical location of the actual or representative label that is specified in the master manufacturing record, we are providing the same flexibility for having a label in the batch production record. Therefore, we are revising the proposed requirement that the batch production record include ''copies of all container labels used'' so that, under final § 111.260(k)(2), the batch production record must include an actual or representative label, or a cross-reference to the physical location for the actual or representative label that is specified in the master manufacturing record.

However, we are not requiring in final § 111.260(k)(2) that the batch production record include the results of examinations conducted during the label operation to ensure that the containers have the correct label that is specified in the master manufacturing record, because this would be redundant to final § 111.260(k)(3).

d. *Final § 111.260(k)(3).* Final § 111.260(k)(3) requires that the documentation of packaging and

labeling operations include the results of any tests or examinations conducted on packaged and labeled dietary supplements (including repackaged or relabeled dietary supplements), or a cross-reference to such results. Final § 111.260(k)(3) combines the proposed requirements of proposed § 111.70(g)(2) which would require that the documentation include the results of examinations conducted in accordance with proposed § 111.70(b)(7), and proposed § 111.70(g)(3) which would require that the documentation include the conclusions from retests conducted in accordance with proposed § 111.70. For consistency with other requirements for documentation that must be in the batch record, final § 111.260(k)(3) requires you to include ''the results of any tests or examinations,'' rather than ''the examination'' (proposed § 111.70(g)(2)) and ''conclusions'' (proposed § 111.70(g)(3)). Final § 111.260(k)(3) also includes editorial revisions associated with combining proposed § 111.70(g)(2) and (g)(3).

We did not receive comments specific to proposed § 111.70(g)(2) or (g)(3).

11. Final § 111.260(l)

Final § 111.260(l) sets forth the requirements for documentation quality control personnel must make at the time of performance and that must be included in the batch production record. Final § 111.260(l) derives from proposed §§ 111.35(i)(2), (j), (m), (o)(2); 111.37(b)(3), (b)(5), and (b)(9); 111.50(c)(1) through (c)(11), (c)(13), (c)(14), (d)(2), (e), and (g); 111.70(b)(6); and 111.70(g).

a. *Final § 111.260(l)(1).* Final § 111.260(l)(1) requires quality control personnel to document at the time of performance the review of the batch production record. Final § 111.260(l)(1) derives from the following proposed regulations:

- § 111.50(d), which would require that the quality control unit review in accordance with § 111.37(b)(5) the batch production record established in § 111.50(c); and
- § 111.50(e), which would require that the quality control unit document at the time of performance in accordance with § 111.37(c), the review performed in accordance with § 111.50(d).

Final § 111.260(l)(1) includes editorial changes associated with the reorganization. We did not receive comments specific to proposed § 111.50(d) or (e).

b. *Final § 111.260(l)(1)(i).* Final § 111.260(l)(1)(i) requires the documentation by quality control personnel to include review of any monitoring operation required under subpart E. Final § 111.260(l)(1)(i) derives from proposed § 111.35(i)(2) which would require that you review, among other things, the results of the monitoring of the in-process control points, steps, or stages to ensure specifications are met. As discussed in section XI of this document (final § 111.123(a)(3)), the final rule requires quality control personnel to review the required monitoring.

We did not receive comments specific to proposed § 111.35(i)(2).

c. *Final § 111.260(l)(1)(ii).* Final § 111.260(l)(1)(ii) requires the documentation by quality control personnel to include the review by quality control personnel of the results of any tests or examinations, including tests or examinations conducted on components, in-process materials, finished batches of dietary supplements, and packaged and labeled dietary supplements. Final § 111.260(l)(1)(ii) derives from the following proposed provisions:

- Proposed § 111.50(e)(1) which would require that the documentation by the quality control unit include review of component, dietary ingredient, and dietary supplement receiving records, including review of testing and examination results and
- Proposed § 111.37(b)(9) which would require, in part, the quality control unit to review all testing results.

(Comment 271) A few comments assert that the proposed requirement that the quality control unit review receiving records as part of its review of the batch record is redundant and should be eliminated. One comment argues that it is unnecessarily burdensome to require the quality control unit to re-review and cross-reference all receiving records, noting that the quality control unit already has performed a review of these records when the components or dietary supplements were received, approved, and released for use. The comment asserts the quality control unit should only have to repeat this review if it is conducting an investigation or a material review.

(Response) We agree with the comments. Therefore, final § 111.260(l)(1)(ii) retains the requirements of proposed §§ 111.37(b)(9) and 111.50(e)(1) to review the results of testing and examination, but does not require quality control personnel to document, as part of the review of the batch record, receiving records for components and dietary supplements.

d. *Final § 111.260(l)(2).* Final § 111.260(l)(2) requires that the documentation by quality control personnel include that quality control personnel approved or rejected any reprocessing or repackaging. Final § 111.260(l)(2) derives from proposed § 111.50(c)(14) which would require that the batch production record include the signature of the quality control unit to document its review of the batch production record and any approval for reprocessing or repackaging. For consistency with other provisions in this final rule (such as final § 111.90), final § 111.260(l)(2) includes a revision that quality control personnel must clearly choose between approving—or rejecting—any reprocessing or repackaging.

We did not receive comments specific to proposed § 111.50(c)(14).

e. *Final § 111.260(l)(3).* Final § 111.260(l)(3) requires the documentation by quality control personnel to include that it approved and released, or rejected, the batch for distribution, including any reprocessed batch. Final § 111.260(l)(3) derives from the following proposed regulations:

- Proposed § 111.37(b)(5) which would require, in part, the quality control unit to review the batch production record to approve the batch for release for distribution;
- Proposed § 111.50(d)(2) which would require the quality control unit not to approve and release for distribution any batch of dietary ingredients or dietary supplement that does not meet all specifications; and
- Proposed § 111.50(g) which would require, in part, the results of the reevaluation by the quality control unit to be documented in the batch production record.

For consistency with other provisions of this final rule (such as final § 111.90), final § 111.260(l)(3) requires that quality control personnel must clearly choose between approving—or rejecting—the batch for distribution. We did not receive comments specific to those parts of proposed §§ 111.37(b)(5) or 111.50(d)(2) that we are setting forth in final § 111.260(l)(3).

f. *Final § 111.260(l)(4).* Final § 111.260(l)(4) requires the batch production record to include documentation, at the time of performance, that quality control personnel approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement. Final § 111.260(l)(4) derives from the following proposed regulations:

- Proposed § 111.37(b)(3) which would require, in part, that the quality

control unit approve or reject all dietary supplements and

• Proposed § 111.70(e) which would require, in part, that any repackaged or relabeled dietary supplement meet all specifications and that the quality control unit must approve or reject their release for distribution.

We did not receive comments specific to those parts of proposed §§ 111.37(b)(3) or 111.70(e) that we are setting forth in final § 111.260(l)(4).

12. Final § 111.260(m)

Final § 111.260(m) requires the batch production record to include documentation, at the time of performance, of any required material review and disposition decision. Final § 111.260(m) derives from the following proposed provisions:

• Proposed § 111.50(c)(13) which would require that the batch production record include any documented review and disposition decision and

• Proposed § 111.35(j) which would require that the person who conducts the material review and makes the disposition decision document that activity, at the time of performance, in the batch production record.

We did not receive comments specific to proposed §§ 111.35(j) or 111.50(c)(13).

13. Final § 111.260(n)

Final § 111.260(n) requires that the batch production record include documentation, at the time of performance, of any reprocessing. We have added this requirement in conjunction with the requirement for written procedures for the quality control operations for approving or rejecting any reprocessing, discussed generally in section IV of this document.

E. Review of Batch Production Record Deviations (Proposed § 111.50(d)(1), (e)(2), (e)(3), and (e)(4))

Proposed §111.50(d)(1) would require, if a batch deviates from the master manufacturing record, including any deviation from specifications, the quality control unit to conduct a material review and make a disposition decision and record any decision in the batch production record. Under final § 111.87 quality control personnel must conduct any required material review and make any required disposition decision; under final § 111.113(a)(2) quality control personnel must conduct a material review and make a disposition decision if a batch deviates from the master manufacturing record, including any deviation from specifications. Given the requirements of final §§ 111.87 and 111.113, it would be redundant to include proposed § 111.50(d)(1) in final subpart I.

Proposed § 111.50(e)(2) would require that the review of the batch production record and documentation by the quality control unit include identification of any deviation from the master manufacturing record that may have caused a batch or any of its components to fail to meet specifications identified in the master production record. Proposed § 111.50(e)(3) would require that the review of the batch production record and documentation by the quality control unit include records of investigations, conclusions, and corrective actions performed in accordance with proposed § 111.50(d). Proposed § 111.50(e)(4) would require that the review of the batch production record and documentation by the quality control unit include the identity of the person qualified by training and experience who performed the investigation in accordance with § 111.50(d).

Each of these requirements is already included in final § 111.140(b)(3) which sets forth the requirements for the documentation that quality control personnel must include for any required material review and disposition decision. In addition, under final § 111.260(m), the batch production record must include documentation of any required material review and disposition decision. Given the requirements of final §§ 111.140(b)(3) and 111.260(m), it would be redundant to include proposed § 111.50(e)(2), (e)(3), and (e)(4) in final subpart I, and we are not including them.

XV. Comments on Production and Process Control System: Requirements for Laboratory Operations (Final Subpart J)

A. Organization of Final Subpart J

In the 2003 CGMP Proposal, the proposed requirements for production and process controls for laboratory operations were set forth in proposed § 111.60(a) through (d). As shown in table 11 of this document, we are reorganizing the requirements for laboratory operations into a distinct subpart (final Subpart J—Production and Process Control System: Requirements for Laboratory Operations). Table 11 lists the sections in final subpart J and identifies the proposed sections that form the basis of the final rule.

TABLE 11.—DERIVATION OF SECTIONS IN FINAL SUBPART J

Final Rule	2003 CGMP Proposal
§ 111.303 What are the requirements under this subpart J for written procedures?	N/A
§ 111.310 What are the requirements for the laboratory facilities that you use?	§ 111.60(a)
§ 111.315 What are the requirements for laboratory control processes?	§ 111.60(b)(1)
§ 111.320 What requirements apply to laboratory methods for testing and examination?	§ 111.60(c) and (d)
§ 111.325 Under this subpart J, what records must you make and keep?	§ 111.60(b)(2) and (b)(3)

B. Highlights of the Changes to the Proposed Requirements for Laboratory Operations

1. Revisions

The final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.

2. Changes Associated With the Reorganization

This subpart contains fewer details, compared to the 2003 CGMP Proposal, regarding the requirements for collecting representative samples and for testing, because these details are set forth elsewhere in this final rule (i.e., in final §§ 111.75 and 111.80) and would be redundant in final subpart J.

3. Changes After Considering Comments

The final rule:

• Includes a new requirement to establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations you conduct to determine whether or not specifications are met.

• Requires you to identify and use the appropriate ''scientifically valid method,'' rather than an appropriate ''validated testing method,'' for each established specification for which testing or examination is required to determine whether the specification is met.

C. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.303)

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section.

Final § 111.303 requires you to establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations you conduct to determine whether specifications are met.

D. What Are the Requirements for the Laboratory Facilities That You Use? (Final § 111.310)

Final § 111.310 requires you to use adequate laboratory facilities to perform whatever testing and examinations are necessary to determine whether: (1) Components that you use meet specifications; (2) in-process specifications are met as specified in the master manufacturing record; and (3) dietary supplements that you manufacture meet specifications. Final § 111.310(a) is substantially similar to proposed § 111.60(a). The requirement for ''adequate laboratory facilities'' is to ensure that the facilities used are designed and suitable for carrying out the necessary tests and examinations. Other CGMP requirements of this final rule would apply to the manufacturer's laboratory facilities, such as Subpart C—Physical Plant and Grounds, and Subpart D—Equipment and Utensils, and should be considered in assessing the adequacy of the laboratory facilities. If the tests and examinations are carried out by an outside laboratory, you will be responsible for ensuring that the test and examinations are adequately performed.

(Comment 272) One comment states that proposed § 111.60(a) would be highly disruptive to the dietary supplement industry and would impose a great burden on companies that traditionally rely on certification of ingredient suppliers. Some comments assert it would be redundant to require testing by companies who are suppliers of dietary ingredients, as well as by companies who receive the dietary supplements, to determine whether the dietary ingredients meet specifications.

(Response) The final rule already includes changes that address the concerns raised by these comments. As discussed in section X of this document regarding final § 111.75(a), the final rule permits the use of certificates of analysis for specifications other than the identity of a dietary ingredient.

E. What Are the Requirements for Laboratory Control Processes? (Final § 111.315)

Final § 111.315 sets forth the minimum laboratory control processes that you must establish and follow. These laboratory control processes must be reviewed and approved by quality control personnel.

1. Final § 111.315(a)

Final § 111.315(a) requires the laboratory control processes you establish and follow to include the use of criteria for establishing appropriate specifications. Final § 111.315(a) is identical to proposed § 111.60(b)(1)(ii).

We did not receive comments specific to proposed § 111.60(b)(1)(ii).

2. Final § 111.315(b)

Final § 111.315(b) requires you to establish and follow laboratory control processes that are reviewed and approved by quality control personnel, including the use of sampling plans for obtaining representative samples, in accordance with subpart E, of: (1) Components, packaging, and labels; (2) in-process materials; (3) finished batches of dietary supplements; (4) product you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier); and (5) packaged and labeled dietary supplements. Final § 111.315(b) derives from proposed § 111.60(b)(1)(iii)(A) through (b)(1)(iii)(E).

Final § 111.315(b) combines the proposed requirements of § 111.60(b)(1)(iii)(A) and (b)(1)(iii)(D) for consistency with final § 111.80(a) which combines the requirements to collect representative samples of components, packaging, and labels. However, for consistency with other requirements established by this final rule, we are separating the requirements to collect representative samples of ''dietary supplements received'' (which the final rule refers to as ''product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier,'' or ''received product'')) from the requirements to collect representative samples of components.

(Comment 273) Some comments note that proposed § 111.60(b)(1)(iii) restates the requirements, already contained in proposed § 111.37(b)(11)(i) through (b)(11)(iv), that the quality control unit collect representative samples. These comments request proposed § 111.60(b)(1)(iii) be deleted, because it is more appropriately described as a quality control function rather than as a laboratory function.

(Response) We disagree that the proposed requirement to use a sampling plan is more appropriately described as a quality control function than as a laboratory function. Under both the proposed and the final rule, the sampling plans that are part of the laboratory control operations are subject to approval by quality control personnel (''unit'' in the proposed rule) but are not developed by quality control personnel. We are making no changes based on this comment.

(Comment 274) One comment asserts sampling can be better accomplished at the point of packaging rather than at a laboratory remote from the packaging operation.

(Response) This comment misinterprets proposed § 111.60(b)(1)(iii) which proposed to establish a process (i.e., the use of a sampling plan) rather than to direct that a particular operating unit (such as a laboratory) collect samples. We are making no changes based on this comment.

3. Final § 111.315(c)

Final § 111.315(c) requires the laboratory control processes you establish and follow include use of criteria for selecting appropriate examination and testing methods. Final § 111.315(c) is identical to proposed § 111.60(b)(1)(i).

(Comment 275) One comment recommends that a contract laboratory hired by a person who is subject to the final rule be able to determine the specific type of test that is most appropriate.

(Response) Nothing in the final rule would preclude you from relying on the recommendation of the contract laboratory in selecting an appropriate test or examination. However, the manufacturer of the dietary supplement has the responsibility to comply with these CGMP requirements, including the requirement to select appropriate tests, regardless of who conducts the tests.

4. Final § 111.315(d)

Final § 111.315(d) requires the laboratory control processes you establish and follow to include use of criteria for selecting standard reference materials used in performing tests and examinations. Final § 111.315(d) derives from proposed § 111.60(b)(1)(iv).

(Comment 276) Several comments support the use of standard reference materials. Some comments distinguish between a reference standard (which they describe as a highly purified

compound that is well characterized and is used in quantitative assays for single chemical entities) and a reference material (which they describe as similar to a reference standard but with less specificity). These comments urge us to recognize the difference between reference standards and reference materials and to require the use of both in the final rule.

(Response) The comments that request we recognize a difference between certain types of reference materials are consistent with proposed § 111.60(b)(1)(iv) and with statements that we made in the preamble to the 2003 CGMP Proposal. We distinguished two general types of reference materials: (1) Compendia reference standards that do not require characterization and (2) noncompendia standards that should be of the highest purity that can be obtained by reasonable effort and that should be thoroughly characterized to ensure their identity, purity, quality, and strength. We recommended you use compendia reference standards whenever possible, and that you establish appropriately characterized in-house materials prepared from representative lots if no compendia reference standard exists.

We also discussed reference materials from the perspective of the type of test or examination. For organoleptic examinations, we described an authenticated plant reference material as material that has been authenticated as the correct plant species and correct plant part(s) by a qualified plant taxonomist. For microscopic and chemical tests (including calibration tests), we described a reference material as a highly purified compound that is well characterized.

To the extent that the comments are recommending that both compendia reference standards and noncompendia reference standards comply with any final rule, this final rule would allow for the use of both compendia reference standards and noncompendia reference standards. However, to the extent that the comments are requesting this final rule require that both types of reference materials be used, we disagree. We see no reason to require, for example, that a firm with access to compendia standards be required to develop noncompendia standards. Likewise, given that we have acknowledged that noncompendia standards may be used, we see no reason to require the use of compendia standards in all circumstances.

(Comment 277) One comment expresses confusion about the preamble discussion of proposed § 111.60(b)(1)(iv) and suggests the preamble specify that reference standards be established appropriate to the assay procedure for which they are used.

(Response) Reference materials should be appropriate to the assay procedure for which they are used.

(Comment 278) Several comments recommend we acknowledge certain reference materials as authoritative sources for botanical ingredients, such as American Herbal Pharmacopoeia, European Pharmacopoeia, and the World Health Organization, in part because other sources include only a limited number of botanicals as supplements. In the comments' view, explicit acknowledgment by FDA would encourage manufacturers to use independent standards, increase CGMP compliance, and show that validation is not limited to quantitative chemical methods.

(Response) We decline to acknowledge certain reference materials as authoritative sources for botanical ingredients. Such a request is outside the scope of this final rule.

(Comment 279) One comment believes we should designate USP to develop appropriate standards.

(Response) This comment is outside the scope of this final rule.

5. Final § 111.315(e)

Final § 111.315(e) requires that the laboratory control processes you must establish and follow include use of test methods and examinations in accordance with established criteria. Final § 111.315(e) derives from proposed § 111.60(b)(1)(vi).

We did not receive comments specific to proposed § 111.60(b)(1)(vi).

F. What Requirements Apply to Laboratory Methods for Testing and Examination? (Final § 111.320)

1. Final § 111.320(a)

Final § 111.320(a) requires you to verify that laboratory examination and testing methodologies are appropriate for their intended use. Final § 111.320(a) is identical to proposed § 111.60(c).

(Comment 280) One comment states that this decision should be made by a qualified person, whether in-house or at a contract laboratory.

(Response) We agree. Nothing in the final rule would preclude you from relying on the judgment of a qualified person at a contract laboratory to satisfy the requirements of final § 111.320(a). We would not consider that a recommendation from a contract laboratory is any different from a recommendation from an operating unit of the manufacturer. However, the manufacturer of the dietary supplement has the responsibility to comply with these CGMP requirements, including the requirement to select appropriate tests, regardless of who conducts the tests.

(Comment 281) One comment suggests modifying proposed § 111.60(c) to add ''reference materials and/or reference standards'' to the list of elements that must be verified to be appropriate for their intended use.

(Response) If reference materials and reference standards are used as part of the test or examination method, then such materials and standards are already required to be verified under the language in proposed § 111.60(c). Thus, there is no need for the modification and we decline to modify the language of final § 111.320(a).

2. Final § 111.320(b)

Final § 111.320(b) requires you to identify and use the appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification is met. Final § 111.320(b) derives from proposed § 111.60(d) which would require you to identify and use an appropriate validated testing method for each established specification for which testing is required to determine whether the specification is met. Final § 111.320(b) includes a provision associated with final § 111.75(h) which provides flexibility to use examinations as well as tests to determine whether specifications are met.

(Comment 282) Many comments express concern about the amount of testing required for the validation of the appropriate test method. Several comments object to the use of the terms ''validations'' and ''validated'' which they assert have a specific meaning in a pharmaceutical context and would be overly burdensome in this rule. Other comments assert that methods already recognized as official standards do not need to be ''validated,'' but simply ''verified'' as to suitability. Some comments suggest substituting ''scientifically valid testing method'' for ''appropriate validated testing method.'' One comment suggests ''qualifications'' replace ''validations.'' Another comment suggests test methods need not be validated if they are ''proven to be suitable under actual conditions of use.'' Another comment suggests adding ''established by the manufacturer'' after ''appropriate validated test method.''

One comment recommends the final rule give companies the flexibility to adopt the method most suitable to the ingredient they are testing, regardless of whether the method is, or is not, an ''official method'' such as those

established by AOAC International or FDA.

(Response) In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12208), we stated that test method validation determines whether a newly-developed or existing test method is accurate, precise, and specific for its intended purpose and involves evaluating the test method on multiple occasions or in multiple test facilities. We explained that official methods, such as AOAC International methods, are validated in collaborative studies using several laboratories under identical conditions and that the AOAC International methods are often cited as ''official validated methods.'' We also explained that other method validations are conducted in a single laboratory by repeating the same test multiple times. Typical validation characteristics include accuracy, precision, specificity, detection limit, quantitation limit, linearity, range, and robustness.

The process of method validation discussed above is a formal process for demonstrating that procedures are suitable for their intended use. Although all methods that are formally validated are considered ''scientifically valid,'' other methods that are based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research can be scientifically valid even if they are not formally ''validated'' in collaborative studies (68 FR 12157 at 12198).

We agree that companies should have flexibility to adopt the method most suitable to the ingredient they are testing. Consistent with the view that we expressed in the preamble to 2003 CGMP Proposal (68 FR 12157 at 12198), we believe that a scientifically valid method is one that is accurate, precise, and specific for its intended purpose. In other words, a scientifically valid method is one that consistently does what it is intended to do.

Because we acknowledge that methods that are based on scientific data or results published in, for example, scientific journals, references, text books, or proprietary research can be scientifically valid even if they are not formally ''validated,'' we are revising proposed § 111.60(d). Under final § 111.320(b) you must identify and use an appropriate ''scientifically valid method'' (rather than a ''validated method'') for each established specification for which testing or examination is required to determine whether the specification is met. However, we continue to recommend that you use tests and examinations that already have been validated when such tests are available.

(Comment 283) One comment specifically asks how much modification of a validated method is allowed before the method must be re-validated by the laboratory. The comment cites an example of moisture testing in which the testing method needs to be modified to provide a more valid moisture reading.

(Response) In the preamble to the 2003 CGMP proposal (68 FR 12157 at 12209), we recommended that, if you modify an officially validated method, you document the reason for the modification and have data to show that the modified method produces results that are at least as accurate and reliable as the established method for the material being tested. We also recommended that you have complete records of any testing and standardization of laboratory reference standards, reagents, and standard solutions that you use in your laboratory operations. We are making no changes to these recommendations in this final rule.

(Comment 284) Several comments request the final rule incorporate by reference authoritative sources of compendial methods.

(Response) We decline this request for the reasons discussed in response to comments 193 and 196.

G. Appropriate Test Method Validation (Proposed § 111.60(b)(1)(v))

Proposed § 111.60(b)(1)(v) would require the laboratory control processes you establish and follow to include the use of appropriate test method validations. Because the final rule does not require that you use a validated method for any tests or examinations that you conduct, we are removing proposed § 111.60(b)(1)(v).

H. Under This Subpart, What Records Must You Make and Keep? (Final § 111.325)

Final § 111.325 sets forth the requirements for records that quality control personnel must make and keep.

1. Final § 111.325(a)

Final § 111.325(a) requires you to make and keep records required under subpart J in accordance with subpart P. Final § 111.325(a) derives from proposed § 111.60(b)(3), which would require you to keep laboratory examination and testing records in accordance with proposed § 111.125. Because final § 111.303 requires you to establish and follow written procedures for laboratory operations, the records you must make and keep under final § 111.325 are not limited to laboratory examination and testing records, but also include the written procedures. Final § 111.325(a) also includes editorial revisions associated with the reorganization and editorial revisions for consistency with the recordkeeping requirements in subparts P.

We did not receive comments specific to proposed § 111.60(b)(3).

2. Final § 111.325(b)(1)

The final rule includes a new requirement (final § 111.303) that you establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations you conduct to determine whether specifications are met. Those written procedures are records. Therefore, final § 111.325(b)(1) requires you to make and keep a record of the written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met.

3. Final § 111.325(b)(2)

Final § 111.325(b)(2) sets forth requirements for documenting that you followed the laboratory methodology established in accordance with this subpart. Final § 111.325(b)(2)(i) requires that the person who conducts the testing and examination document, at the time of performance, that laboratory methodology established in accordance with this subpart is followed. Final § 111.325(b)(2)(ii) requires that the documentation include the results of the testing and examination. Final § 111.325(b)(2) derives from proposed § 111.60(b)(2) with revisions associated with the reorganization.

(Comment 285) One comment states that, without appropriate documentation, there would be no assurance that the appropriate testing was indeed performed and that the product's identity, purity, quality, strength, and composition are what they are represented to be.

(Response) We agree and have retained the requirement in this final provision.

XVI. Comments on the Production and Process Control System: Requirements for Manufacturing Operations (Final Subpart K)

A. Organization of Final Subpart K

In the 2003 CGMP Proposal, the requirements for manufacturing operations were set forth in § 111.65. As shown in table 12 of this document, we are establishing the requirements for

manufacturing operations in a distinct subpart (final Subpart K—Production and Process Control System: Requirements for Manufacturing Operations). In addition, we are incorporating some requirements from proposed § 111.74 relating to rejected components, dietary supplements, and packaging and labels into final subpart K. Table 12 lists the sections in final subpart K and identifies the proposed sections that form the basis of the final rule.

TABLE 12.—DERIVATION OF SECTIONS IN FINAL SUBPART K

Final Rule	2003 CGMP Proposal
§ 111.353 What are the requirements under this subpart K for written procedures?	N/A
§ 111.355 What are the design requirements for manufacturing operations?	§ 111.65(a)
§ 111.360 What are the requirements for sanitation?	§ 111.65(b)
§ 111.365 What precautions must you take to prevent contamination?	§ 111.65(c)
§ 111.370 What requirements apply to rejected dietary supplements?	§ 111.74
§ 111.375 Under this subpart K, what records must you make and keep?	N/A

B. Highlights of Changes to the Proposed Requirements for Manufacturing Operations

1. Revisions

The final rule:

- Applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1 and
- Reflects changes relevant to this subpart that we are making to final subpart C concerning water standards.

2. Changes Made After Considering Comments

The final rule requires written procedures for manufacturing operations.

3. Revisions Associated With the Reorganization

The final rule sets forth in final § 111.90, rather than in subpart K, the requirements for in-process adjustments or reprocessing.

C. General Comments on Manufacturing Operations

(Comment 286) Some comments support proposed § 111.65 as a ''good model'' for an appropriate level of flexibility, noting that proposed § 111.65 clearly states the requirements and presents relevant factors that must be considered when determining how to best meet the requirements of the rule.

(Response) We acknowledge these comments and utilize many elements of proposed § 111.65 in final § 111.355.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.353)

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section.

We are including a new provision, final § 111.353, to require that you establish and follow written procedures for manufacturing operations.

E. What Are the Design Requirements for Manufacturing Operations? (Final § 111.355)

Final § 111.355 requires you to design or select manufacturing processes to ensure that product specifications are consistently met. Final § 111.355 derives from proposed § 111.65(a) which would require you to design or select manufacturing processes to ensure that dietary supplement specifications are consistently achieved. Final § 111.355 refers to ''product specifications'' rather than ''dietary supplement specifications'' to conform with final § 111.70(e). We have substituted the word ''met'' for ''achieved'' to comply with plain language initiatives and to be consistent with other provisions.

We did not receive comments specific to proposed § 111.65(a).

F. What Are the Requirements for Sanitation? (Final § 111.360)

Final § 111.360 requires you to conduct all manufacturing operations in accordance with adequate sanitation principles. Final § 111.360 derives from proposed § 111.65(b). We did not receive comments specific to proposed § 111.65(b).

G. What Precautions Must You Take to Prevent Contamination? (Final § 111.365)

Final § 111.365 requires you to take all necessary precautions during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements. Final § 111.365 derives from proposed § 111.65(c)(1) through (c)(11).

1. Final § 111.365(a)

Final § 111.365(a) requires that the necessary precautions include performing manufacturing operations under conditions and controls that protect against the potential for growth of microorganisms and the potential for contamination. Final § 111.365(a) derives from proposed § 111.65(c)(1).

(Comment 287) One comment contends that the requirement in proposed § 111.65(c)(1) to protect ''against the potential for growth of microorganisms,'' does not take into account processes that have a kill step. The comment recommends that proposed § 111.65(c)(1) be revised to be more consistent with § 110.80(b)(2) and state, ''performing manufacturing operations under such conditions and controls as are necessary to minimize the potential for the growth of undesirable microorganisms, or for the contamination of the product.''

(Response) We decline to modify final § 111.365(a) as requested by the comment because the provision accomplishes what is requested by the comment. We defined ''microorganism'' in the 2003 CGMP Proposal similar to how we describe ''undesirable microorganisms'' in § 110.3(i). Further, we decline to use the words ''minimize the potential for growth'' instead of ''protect against the potential for growth'' because the word ''minimize'' suggests a lesser standard than ''protect against'' the potential for growth of microorganisms.

We would consider that you are not complying with the final rule if you do not perform manufacturing operations under conditions and controls that protect against the potential for growth of microorganisms and the potential for contamination, regardless of whether you use a kill step. Although a kill step may be necessary in some circumstances, it is not a substitute for conditions and controls that protect against the potential for growth of microorganisms and the potential for contamination. Therefore, we decline to make the change requested by this comment.

2. Final § 111.365(b)

Final § 111.365(b) requires that necessary precautions include washing or cleaning components that contain soil or other contaminants. Final § 111.365(b) is identical to proposed § 111.65(c)(2). We did not receive comments specific to proposed § 111.65(c)(2).

3. Final 111.365(c)

Final § 111.365(c) requires that the necessary precautions include using water that, at a minimum, complies with the applicable Federal, State, and local requirements and does not contaminate the dietary supplement when the water may become a component of the finished batch of dietary supplement.

The proposed requirements would set forth parallel requirements for water that is used in the manufacture of a dietary supplement for both your physical plant (proposed § 111.15(d)(2)) and for manufacturing operations (proposed § 111.65(c)(3)). Thus, proposed § 111.15(d)(2) would require that water that contacts components, dietary ingredients, dietary supplements, or any contact surface must, at a minimum, comply with the NPDW regulations prescribed by the Environmental Protection Agency under 40 CFR part 141 and any State and local requirements.

As discussed in section VIII of this document (final § 111.15(e)(2) in subpart C), we are revising proposed § 111.15(d)(2) to require in the final rule that water, used in the manufacture of a dietary supplement in a manner such that the water may become a component of the dietary supplement, i.e., when such water contacts components, dietary supplements, or any contact surface, must, at a minimum, comply with applicable Federal, State, and local requirements and not contaminate the dietary supplement. Given the parallel nature of proposed § 111.65(c)(3) and proposed § 111.15(d)(2), we are revising proposed § 111.65(c) to be consistent with the revisions we are making to proposed § 111.15(d)(2) (final § 111.15(e)(2)).

Final § 111.365(c) also includes grammatical changes consistent with the structure of final § 111.365.

(Comment 288) One comment asks that the words ''or equivalent quality water'' be added to ''water that meets the National Primary Drinking Water regulations'' in proposed § 111.65(c)(3) to allow for ingredients manufactured in facilities outside the United States.

(Response) As stated in response to comment 91, dietary supplements manufactured in a foreign country would be subject to the requirements of this final rule. Although the Environmental Protection Agency NPDW regulations would not apply to a foreign manufacturer, the foreign manufacturer would need to use water that is of a standard required in this final rule and that achieves the same level of performance required of domestic manufacturers. The water used by the foreign facility must not contaminate the dietary supplement that is manufactured. We decline to add ''or equivalent water quality'' because that would suggest domestic firms would not need to follow whatever Federal, State, and local requirements are applicable.

(Comment 289) One comment recommends that proposed § 111.65(c)(3) be revised to be consistent with proposed § 111.15(d)(1), which would require you to provide water that is safe and of adequate sanitary quality, at suitable temperatures, and under pressure as needed, in all areas where water is necessary for: (1) Manufacturing dietary ingredients or dietary supplements; (2) making ice that comes in contact with components, dietary ingredients, dietary supplements, or contact surfaces; (3) cleaning any surface; and (4) employee bathrooms and hand-washing facilities.

(Response) We do not agree with the comment that we should be consistent in the water requirement related to proposed § 111.15(d)(1) and the requirement in proposed § 111.65(c)(3). The requirement in proposed § 111.15(d)(1) describes a variety of manufacturing operations where water is used. For example, water that is safe and of adequate sanitary quality, as described in the proposed rule, for purposes of manufacturing dietary supplements or that comes into contact with a dietary supplement would be water that would have been required to comply with the requirement in proposed § 111.15(d)(2). Under the proposed rule and under the final rule, if such water is subject to Environmental Protection Agency NPDW, then the water must meet Environmental Protection Agency NPDW requirements at point of use. Proposed § 111.15(d)(1) has been revised and simplified in final § 111.15(e)(1) to require you to provide water that is safe and sanitary, at suitable temperatures, and under pressure as needed, for all uses where water does not become a component of the dietary supplement. Water that is safe and sanitary for cleaning the floor in a facility would not need to meet standards for drinking water, but such water could not be a source of contamination of the dietary supplement. The standard ''safe and sanitary'' in final § 111.15(e)(1) allows some flexibility for the manufacturer in deciding what water it can use in various operations for which no other requirements in this final rule apply. The requirements of final § 111.365(c) are consistent with the changes in final § 111.15(e).

4. Final § 111.365(d)

Final § 111.365(d) requires that the necessary precautions you take during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements include performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated components. Final § 111.365(d) derives from proposed § 111.65(c)(4).

(Comment 290) One comment asserts that requirements for testing belong in proposed § 111.25 (proposed requirements for equipment and utensils) rather than in proposed § 111.65 (proposed requirements for manufacturing operations).

(Response) In our discussion of proposed § 111.65(c)(4) in the 2003 CGMP Proposal (68 FR 12157 at 12210), we stated that you consider identifying those areas in the processing and production areas where chemical, microbial, or other forms of contamination are most likely to occur. We also stated that chemical, microbial, or other testing is necessary to identify areas where sanitation measures have not been adequate or where products may become adulterated. These remarks reflect that the proposed requirement in proposed § 111.65(c)(4) is directed to facilities rather than to equipment and utensils. For example, under proposed § 111.65(c)(4), we encouraged you to establish a testing program that monitors levels of microorganisms at key places in your physical plant where you process and produce your products. Thus, we disagree with the comment that the testing requirements belong in proposed § 111.25 and are not making any changes in final § 111.365(d).

5. Final § 111.365(e)

Final § 111.365(e) requires that the necessary precautions you take during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements include sterilizing, pasteurizing, freezing, refrigerating, controlling hydrogen-ion concentration (pH), controlling humidity, controlling water activity (a_w), or using any other effective means to remove, destroy, or prevent the growth of microorganisms, and prevent

decomposition. Final § 111.365(e) derives from proposed § 111.65(c)(5).

(Comment 291) One comment asserts that only sanitary practices are needed to prevent microbial contamination or decomposition, and, therefore, requests that we clarify the processes listed in proposed § 111.65(c)(5) are optional.

(Response) We disagree with this comment. Good sanitary practices are important, but they are not the only precaution to take to prevent a component or dietary supplement from contamination with microorganisms. In the preamble to the 2003 CGMP Proposal, we gave the example of bovine colostrum, which is the lacteal secretion that precedes milk after a cow gives birth and is a substance that is used in dietary supplements. We also stated that we consider that bovine colostrum likely presents the same potential health risks as bovine milk, which can contain pathogenic organisms capable of causing diseases in man such as tuberculosis, undulant fever, or gastrointestinal disease and, thus, must be pasteurized (21 CFR 1240.61). Under final § 111.365(e) you must sterilize or pasteurize bovine colostrums, or take other steps, to remove or destroy microorganisms that could be present in bovine colostrum. Under final § 111.365(e) we list various ways that, depending upon the particular situation, would be effective in removing, destroying, or preventing the growth of microorganisms and preventing decomposition. You must decide for your given operation what means to use to remove, destroy, or prevent the growth of microorganisms and prevent deterioration of your components and dietary supplements so that you ensure the quality of the dietary supplement.

(Comment 292) Some comments recommend adding ''irradiating'' to the list of practices to prevent the growth of microorganisms in proposed § 111.65(c)(5) similar to the industry CGMP provision, ''Production and Process Controls,'' section (d)(5), published in the 1997 ANPRM.

(Response) We decline to revise the provision as suggested by these comments. We are not adding ''irradiating'' to the list of practices because, at this time, irradiation of dietary ingredients and dietary supplements, as a means to reduce or eliminate microbial loads, is not permitted. CFSAN is currently reviewing the use of irradiation for the control of microbial contamination on dietary supplements and ingredients (including dietary ingredients) used in the manufacture of dietary supplements (68 FR 25048, May 9, 2003). If we authorize this use of irradiation you could then use irradiation in compliance with that rule to comply with final § 111.365(e) as an ''other effective means.''

6. Final § 111.365(f)

Final § 111.365(f) requires that the necessary precautions you take during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements include holding components and dietary supplements that can support the rapid growth of microorganisms of public health significance in a manner that prevents the components and dietary supplements from becoming adulterated. Final § 111.365(f) derives from proposed § 111.65(c)(6). We did not receive comments specific to proposed § 111.65(c)(6).

7. Final § 111.365(g)

Final § 111.365(g) requires that the necessary precautions you take during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements include identifying and holding any components or dietary supplements, for which a material review and disposition decision is required, in a manner that protects components or dietary supplements that are not under a material review against contamination and mixups with those under a material review. Final § 111.365(g) is substantially similar to proposed § 111.65(c)(7). We did not receive comments specific to proposed § 111.65(c)(7).

8. Final § 111.365(h)

Final § 111.365(h) requires that the necessary precautions you take during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements include performing mechanical manufacturing steps (such as cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) by any effective means to protect the dietary supplements against contamination. Final § 111.365(h) derives from proposed § 111.65(c)(8). Such steps must include consideration of: (1) Cleaning and sanitizing contact surfaces, (2) using temperature controls, and (3) using time controls.

(Comment 293) One comment suggests that the time controls required in proposed § 111.65(c)(8)(iii) are not always necessary.

(Response) As written, proposed § 111.65(c)(8) acknowledges that time controls are not always necessary, because the provision requires that you consider using time controls, and implement them if they are necessary to prevent contamination of components or dietary supplements. Final § 111.65(h) retains this same language.

9. Final § 111.365(i)

Final § 111.365(i) requires that the necessary precautions you take during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements include using effective measures to protect against the inclusion of metal or other foreign material in components or dietary supplements. Compliance with this requirement must include consideration of the use of: (1) Filters or strainers, (2) traps, (3) magnets, or (4) electronic metal detectors. Final § 111.365(i) derives from proposed § 111.65(c)(9).

(Comment 294) One comment contends it is sufficient to require in proposed § 111.65(c)(9) that manufacturers inspect their equipment before and after use to determine if any piece is missing, and if so, the entire batch should be disposed of. The comment states metal detection devices are not 100 percent effective and that inspection of equipment before and after use would be preferable.

(Response) We disagree with the comment. As discussed in the 2003 CGMP Proposal, the purpose behind proposed § 111.65(c)(9) is to ensure that no metal or foreign material becomes a source of possible contamination and not to establish mechanisms to be used after contamination has or is suspected to have occurred (68 FR 12157 at 12211). The source of metal contamination is not limited to manufacturing equipment. For example, metal contamination could occur through using utensils such as metal brushes during processing of natural products. It would be impractical to determine whether contamination has occurred by examining the brush.

10. Final § 111.365(j)

Final § 111.365(j) requires that the necessary precautions you take during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements include segregating and identifying all containers for a specific batch of dietary supplements to identify their contents and, when necessary, the phase of manufacturing. Final § 111.365(j) derives from proposed § 111.65(c)(10). We did not receive comments specific to proposed § 111.65(c)(10).

11. Final § 111.365(k)

Final § 111.365(k) requires that the necessary precautions you take during the manufacture of a dietary supplement

to prevent contamination of components or dietary supplements include identifying all processing lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number and, when necessary, the phase of manufacturing. Final § 111.365(k) derives from proposed § 111.65(c)(11).

(Comment 295) One comment suggests continuous processes should be excluded from the requirement in proposed § 111.65(c)(11) to identify specific batch or lot numbers. The comment explains that in continuous bulk operations for manufacturing dietary ingredients, the batch or lot number often is not identified until after the materials have been blended and moved into a storage bin.

(Response) We are making no changes to proposed § 111.65(c)(11) in final § 111.365(k) because the comment describes a situation where the manufacturer is manufacturing a dietary ingredient, and the final rule does not apply to the manufacture of a ''dietary ingredient'' within the meaning of section 201(ff) of the act.

H. What Requirements Apply to Rejected Dietary Supplements? (Final § 111.370)

Final § 111.370 requires you to clearly identify, hold, and control under a quarantine system for appropriate disposition any dietary supplement that is rejected and unsuitable for use in manufacturing, packaging, or label operations. Final § 111.370 derives from proposed § 111.74 which would require that you clearly identify, hold, and control under a quarantine system any component, dietary ingredient, dietary supplement, packaging, and label that is rejected and unsuitable for use in manufacturing, packaging, or label operations. Because the requirements regarding components, packaging, and labels that are rejected and unsuitable for use are already set forth in final § 111.170, final § 111.370 addresses only the requirements for dietary supplements.

We did not receive comments specific to proposed § 111.74.

I. Under This Subpart, What Records Must You Make and Keep? (Final § 111.375)

In order to ensure that records are maintained as required under subpart P, we are adding a new § 111.375. This section requires that you make and keep records of the written procedures you establish for manufacturing operations. These written procedures are required under final § 111.353.

XVII. Comments on the Production and Process Control System: Requirements for Packaging and Labeling Operations (Final Subpart L)

A. Organization of Final Subpart L

In the 2003 CGMP Proposal, the requirements for packaging and labeling operations were set forth in § 111.70. As shown in table 13 of this document, the final rule reorganizes the requirements related to quality control operations into a distinct subpart (final Subpart L—Production and Process Control System: Requirements for Packaging and Labeling Operations). Table 13 lists the sections in final subpart L and identifies the proposed sections that form the basis of the final rule.

TABLE 13.—DERIVATION OF SECTIONS IN FINAL SUBPART L

Final Rule	2003 CGMP Proposal
§ 111.403 What are the requirements under this subpart L for written procedures?	N/A
§111.410 What requirements apply to packaging and labels?	§ 111.70(a), (b)(6), and (f)
§ 111.415 What requirements apply to filling, assembling, packaging, labeling, and related operations?	§ 111.70(b)
§111.420 What requirements apply to repackaging and relabeling?	§ 111.70(d) and (e)
§111.425 What requirements apply to a packaged and labeled dietary supplement that is rejected for distribution?	§ 111.74
§ 111.430 Under this subpart L, what records must you make and keep?	§ 111.70(g) and (h)

B. Highlights of Changes to the Proposed Requirements for Packaging and Labeling Operations

1. Revisions

The final rule:

- Reflects that the final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.
- Reflects that the labeling requirements of the rule address the operation of putting the label specified in the master manufacturing record on the final product.
- Clarifies the applicability of the rule to labeling operations.

2. Changes Associated With the Reorganization

We are moving to final § 111.260(k) in subpart I the requirements for the documentation, in the batch production record, of packaging and labeling operations (proposed § 111.70(g)).

3. Changes After Considering Comments

The final rule:

- Requires you to establish and follow written procedures for packaging and labeling operations.
- Provides for an exception to the requirements for label reconciliation for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations.
- Clarifies the requirement for ''retesting or re-examining'' any repackaged or relabeled dietary supplements, i.e., consistent with final § 111.75(g) you must examine a representative sample of each batch of repackaged or relabeled dietary supplements to determine whether repackaged or relabeled dietary supplements meet all specifications established in accordance with § 111.70(g).

C. General Comments on Proposed Requirements for Packaging and Labeling Operations

(Comment 296) Some comments assert that the proposed packaging and labeling requirements are unnecessarily stringent for dietary ingredients, because the potential for abuse is primarily at the final product stage.

(Response) To the extent that the comment is saying that a dietary ingredient manufacturer who manufactures, packages, labels, and holds a dietary ingredient that is further processed and incorporated into a dietary supplement by another person should not have to comply with the packaging and labeling requirements in subpart L, we agree. We are modifying the scope of the rule as to who is subject to the CGMP requirements, as discussed in section VI of this document (subpart A). The final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.

(Comment 297) Several comments assert that it is imperative that a dietary supplement contain what it purports on its label. Some comments state that the

amounts of ingredients listed on the label must accurately reflect what is in the package.

(Response) To the extent that the comments are suggesting that there need to be requirements for labeling operations as part of CGMP to ensure that the label applied to the dietary supplement is the label specified in the master manufacturing record for the finished product, we agree. To the extent that the comments suggest that CGMP requirements should ensure the quality of the dietary supplement manufactured, we also agree. If consumers believe that dietary supplements contain the ingredients as labeled, as with any other product they purchase, then CGMP requirements should help to ensure that dietary supplements are manufactured consistently to ensure the quality of the dietary supplement and to help ensure the proper identity and amount of ingredients identified on the label.

D. General Comments on Requirements for What Must Be on the Product Label Rather Than for Labeling Operations

(Comment 298) Some comments express disappointment that the 2003 CGMP Proposal does not address product claims included on product labels. These comments state that, if FDA is not going to review label claims, it should, at a minimum, require the following statement be placed on dietary supplement products: ''This product has not been reviewed for safety and efficacy by the FDA.'' These comments assert that such a statement should be included on all dietary supplement products, regardless of whether the product makes structure/function claims. These comments also recommend that dietary supplement labeling encourage consumers to share information about their use of the dietary supplements with their pharmacists and physicians and encourage consumers to seek the input of a health care provider if symptoms that prompted use of the dietary supplement are not resolved.

One comment requests we establish specific label content to include on dietary supplement labels. The comment asserts that the technology and mechanical tools exist to produce expanded labeling for dietary supplements efficiently and cost-effectively. The comment asserts that the content should include a complete listing of ingredients, relative percentages, batch or lot number, intended use, safety information, directions, and product information. Specifically, the comment supports the labeling recommendations of the U.S. Department of Health and Human Services (HHS), Office of the Inspector General (OIG) ''Dietary Supplement Labels: Key Elements,'' March 2003, publication no. OEI–01–01–00120, available at *http://oig.hhs.gov/oei/reports/oei–01–01–00120.pdf*) (Ref. 34). The comment endorses the HHS/OIG recommendations, with the addition of batch or lot number on the label. The comment also endorses the OIG's proposed label presentation which calls for: (1) A standardized format with similar types of information in a similar order across supplements; (2) distinct product features to assist consumers in distinguishing supplements from other health care products; (3) readability, with language and visual cues that are easily understood by consumers; (4) balance to present information in a fair and balanced format that omits marketing and sales pitches; and (5) constructive use of space whereby innovative packaging is employed to expand label space.

Several comments address whether we should permit manufacturers to state on their products that the manufacturer of the product is in compliance with FDA CGMP requirements. Several comments assert that a CGMP statement on labels should not be allowed. These comments assert that the proposed ''made in a CGMP facility'' language is fraught with potential misuse, and that the potential for confusion is overwhelming. These comments state that the rule also should be modified to exclude other similar statements such as ''produced using good laboratory practices,'' ''produced using good practices,'' or ''produced in compliance with USP good manufacturing practices.'' According to these comments, similar statements currently appear on dietary supplement labels and also may be misleading. These comments assert that CGMP requirements are not voluntary and should not be marketed as such.

Some comments state that a voluntary label statement that a dietary supplement complies with CGMP should be allowed. According to these comments, there are several third party organizations such as USP and National Nutritional Foods Association (NNFA) that have proposed or established CGMP requirements as rigorous as, or more rigorous than, those proposed by FDA. These comments assert that a voluntary statement that characterizes the nature of the GMP compliance should be allowed.

(Response) The comments related to requests about specific label content, such as ingredient listing, relative percentage of ingredients, intended use, safety information, label format, use of label space, and directions and product information are outside the scope of this final rule. Further, with respect to requiring specific statements about dietary supplement product, such as, ''This product has not been reviewed for safety and efficacy by the FDA,'' or ''This product has been produced using good manufacturing practice,'' we have stated previously that the manufacturer is responsible for ensuring that any voluntary labeling statements on its dietary supplement products are truthful and not misleading (68 FR 12157 at 12164). We would review the lawfulness of such statements under sections 403(a)(1) and 201(n) of the act.

We did not propose to require any specific statements. We stated that an unqualified statement such as ''produced in compliance with dietary supplement current good manufacturing practice requirements,'' without more, could suggest a product may be safe and effective or somehow superior to other dietary supplement products that are subject to the same CGMP requirements (id.). Further, we stated that such a statement would likely be considered misleading by us under sections 403(a)(1) and 201(n) of the act, but that including language clarifying to consumers that all dietary supplements must be manufactured in compliance with CGMP requirements and that such compliance does not mean that the dietary supplement is safe or effective may be a way to cure that unqualified statement (id.). Thus, we are not prohibiting voluntary statements on the dietary supplement label, provided that such statements are truthful and not misleading.

(Comment 299) Some comments assert that the labeling standards found in the 2003 CGMP Proposal should be uniformly applied across manufacturers, regardless of size, because consumers are unlikely to differentiate between small companies and large ones when selecting dietary supplements. These comments assert that we should, therefore, only allow 1 year for labeling compliance for all manufacturers regardless of their size.

Some comments assert that small manufacturers are more likely to suffer competitively if their labels lack important ingredient and other information relative to labeling employed by their larger competitors. These comments argue that enhanced labeling is a cost-effective packaging feature and should not represent a significant cost burden when outsourced to a qualified print-packaging vendor. Moreover, labels already represent a budgeted cost item

for dietary supplement producers. Labels with additional content would add little to manufacturer overhead.

(Response) These comments may have misinterpreted the 2003 CGMP Proposal. The CGMP requirements do not impose any requirements for the specific content of the label. We discuss the requirements necessary to determine the complete manufacturing history and control of a packaged and labeled dietary supplement through distribution in this subpart in our discussion on final § 111.410(d). To the extent that businesses with fewer than 500 employees want to comply with the CGMP requirements for labeling operations in a shorter timeframe than what we are allowing in this final rule, such businesses may do so. However, to assist businesses with fewer than 500 employees in complying with dietary supplement CGMPs, we are giving businesses with fewer than 500 but 20 or more employees a compliance date of 24 months after the date of publication of this final rule, and we are giving businesses with fewer than 20 employees a compliance date of 36 months after the date of publication of this final rule.

E. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.403)

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section.

Final § 111.403 requires you to establish and follow written procedures for packaging and labeling operations. Under final 111.430(b), relating to records you must make and keep, we require that you make and keep records of such written procedures.

F. What Requirements Apply to Packaging and Labels? (Final § 111.410)

1. Final § 111.410(a)

Final § 111.410(a) requires that you take necessary actions to determine whether the packaging for dietary supplements meets specifications so that the condition of the packaging will ensure the quality of your dietary supplements. Final § 111.410(a) is similar to proposed § 111.70(a) which would require you to take necessary actions to ensure that each packaging container for holding dietary ingredients or dietary supplements meets specifications so that the condition of the packaging container will not contaminate your dietary supplements or cause them to deteriorate. We have made changes to be consistent with final § 111.70 and the definition of ''quality'' by substituting the phrase ''ensure the quality of your dietary supplement'' instead of using the words ''contamination'' and ''deterioration'' which would be encompassed in the definition of ''quality.'' We are deleting the words ''container'' and ''holding'' from final § 111.410(a) to emphasize that all packaging must meet specifications and ensure the quality of the dietary supplement.

(Comment 300) One comment requests the removal of the word ''each'' from proposed § 111.70(a) because the inclusion of the word mandates that each and every container, rather than a representative sample, be inspected.

(Response) Because the final rule only requires the use of representative samples to ensure compliance, as provided in final § 111.80, to reduce the potential for confusion, we are deleting the word ''each'' and making associated grammatical revisions.

(Comment 301) Some comments request we clarify our expectations under proposed § 111.70(a) with respect to substantiating that packaging containers meet specifications and will not contaminate dietary supplements. The comments assert that it is not necessary for a manufacturer to test these types of products proactively, and that a continuing product guarantee combined with a statement of intended use from the manufacturer of the packaging material should suffice to meet the proposed requirements. The comments assert this is consistent with expected practice in other industries that FDA regulates.

(Response) Final § 111.410(a) reiterates the requirement of final § 111.70(d) to establish packaging specifications and the requirement of final § 111.75(f)(1) to determine whether packaging specifications are met. Under final § 111.75(f)(1), to determine whether packaging meets its specifications, you must conduct a visual identification of the containers and closures and review the supplier's invoice, guarantee, or certification. Thus, the final rule does not require that you test packaging proactively, and does allow you to rely on documentation such as a continuing product guarantee combined with a statement of intended use from the manufacturer of the packaging.

As we discussed in the preamble to 2003 CGMP Proposal (68 FR 12157 at 12212), proposed § 111.70(a) would require you to take into account factors such as whether your product is sensitive to light when setting specifications for packaging. Other factors to consider include whether your product is sensitive to moisture or could interact with certain kinds of packaging. (For other requirements related to packaging, see final §§ 111.70(d), (f), (g), and 111.160.)

2. Final § 111.410(b)

Final § 111.410(b) requires you to control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies, except that label reconciliation is not required for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations. Final § 111.410(b) derives from proposed § 111.70(f)(1) which would require you to control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies.

(Comment 302) Some comments assert that comprehensive label reconciliation should not be required if appropriate electronic controls are instituted to ensure that correct labels are used during labeling operations. The comments state this alternative is permitted for labeling operations for drug products, which are generally identical or similar in nature to labeling operations for dietary supplements. As such, the comments assert that the same flexibility should be afforded to dietary supplement manufacturers.

(Response) We agree with these comments and the revisions are reflected in final § 111.410(b) (proposed § 111.70(f)(1)).

3. Final § 111.410(c)

Final § 111.410(c) requires you to examine, before packaging and labeling operations, packaging and labels for each batch of dietary supplement to determine whether the packaging and labels conform to the master manufacturing record. Final § 111.410(c) derives from proposed § 111.70(f)(2). We did not receive comments specific to proposed § 111.70(f)(2).

4. Final § 111.410(d)

Final § 111.410(d) requires you to be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution. We are revising the language of proposed § 111.70(b)(6) and including in final § 111.410 the similar requirement stated in proposed § 111.70(b)(6). Section 111.410 is where we chose to place this requirement because it is likely that you will affix the batch, lot, or control

number that you used for the finished batch of dietary supplement on the immediate container or on the product label as the means to trace the product through distribution, although this is not required. Other means are acceptable besides the use of a batch, lot, or control number.

(Comment 303) Some comments assert that we do not propose in the 2003 CGMP Proposal the affixing of a lot number to the container of product marketed to the consumer. These comments assert that all the recordkeeping in the 2003 CGMP Proposal is of little value unless issues can be traced back from the individual container, perhaps received from a customer complaint, to a specific batch. These comments state that such labeling should be a requirement.

(Response) We agree that it is necessary to be able to trace a dietary supplement in distribution to a specific batch or lot of product. We disagree that we did not provide any requirements in the 2003 CGMP Proposal that would require you to be able to trace a distributed dietary supplement to a specific batch or lot.

In proposed § 111.70(b)(6) we stated that a batch, lot, or control number is necessary for you to trace the manufacturing history for a particular batch, which will help you investigate and correct any safety problems for a batch or to recall a dietary supplement. We discussed the fact that, without such a batch, lot, or control number, consumers would be unable to determine which product was the subject of a recall and they would not know which product to stop using, or there would be a need to recall more product than otherwise may be necessary (68 FR 12157 at 12212).

We also proposed several other requirements related to the need to be able to trace the components, packaging, and labeling used in the manufacture of a dietary supplement with the distributed dietary supplement. Under proposed § 111.40(a) (with respect to components and dietary supplements) and proposed § 111.40(b)(3) (with respect to packaging and labeling) we would require you to identify each lot of product received in a shipment in a manner to allow you to trace the shipment lot to the dietary supplement manufactured and distributed. In the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12202), we stated that using a unique identifier throughout the manufacturing process will make it possible to track and account for components and dietary supplements received to any necessary investigation of consumer complaints. In proposed § 111.50(c)(1) we provided that the batch production record must include a batch, lot, or control number, and in proposed § 111.50(c)(5) we provided that the batch production record must include the shipment lot unique identifier of each component, dietary ingredient, dietary supplement, packaging, and label used. Further, in proposed § 111.85(d), we required that you conduct an investigation if a returned dietary supplement implicates associated batches. Thus, we proposed to require that you be able to trace a dietary supplement through distribution. However, we did not require you to use a specific mechanism, such as affixing a batch, lot, or control number to the immediate container or product label. Under the 2003 CGMP Proposal, the manufacturer would have flexibility to determine the method to trace its product in distribution to the batch, lot, or control number assigned to the finished batch or lot of dietary supplement.

In final § 111.415(f), we require you to assign a batch, lot, or control number to: (1) Each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement and (2) each lot of dietary supplement, from a finished batch of dietary supplement, that you distribute to another person for packaging or labeling. We do not require you to affix this batch, lot, or control number to the immediate container or the product label. Instead, we provide flexibility for you to determine how you track the batch, lot, or control number you assign to each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement, and each lot of dietary supplement from a finished batch of dietary supplement you distribute to another person for packaging or labeling, to distributed dietary supplements. To clarify that we do not require you to affix a batch, lot, or control number on the immediate container or product label, final § 111.410(d) provides that you must be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution by a method of your choice. For example, a dietary supplement manufacturer may make one type of product that it distributes to a select few customers and may be able to trace its dietary supplement using dates on distribution records to such customers, or may use different containers or labeling, other than a batch, lot, or control number that is affixed to the label.

We are retaining the use of a unique identifier in final §§ 111.155(d), 111.160(d), and 111.260(a), (d), and (k). These requirements relate to the tracking of a component, packaging, labeling, or dietary supplement throughout the manufacturing process. The use of a batch, lot, or control number or other unique identifier, as required, for product in the manufacturing process is needed for tracking components, packaging, and labels used to manufacture, package, or label a dietary supplement so that once a batch is identified, the components, packaging, and labels used in a batch will also be known. But by contrast, when the distribution of a final product may be distributed to a few select customers, or where every unique batch is placed in a different type of container, there may not be a need to use batch, lot, or control numbers affixed to the immediate container or product labels to be able to trace the product.

This final rule will enhance the benefits of the new statutory requirement for mandatory reporting to FDA of serious adverse events as the result of the enactment of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), signed into law on December 22, 2006. This final rule will facilitate the additional traceback activities taking place as a result of the additional serious adverse events discovered through mandatory reporting. We will evaluate such mandatory reports for patterns or ''signals'' of problems with particular products so that further harm to consumers may be prevented by removing the products and, in some cases, related products from the marketplace. This cannot be done without first quickly and accurately identifying the products of interest. To efficiently determine which specific products or group of products are associated with the serious (or non-serious) adverse event report, traceback ability is crucial. This final rule includes requirements that will provide the information needed to quickly and accurately conduct a sufficient traceback. The provisions that require maintenance of records for production processes include records such as batch records, unique identifiers, and master manufacturing records. The recordkeeping provisions of this final rule give us access to those records, so we will have an enhanced ability to investigate the serious adverse events reported to us, using records such as information on ingredients, processing, storage, composition, and distribution. This enhanced ability to track information related to serious adverse events will increase both the accuracy and the speed of the response to such

events, which may in many cases reduce the number of illnesses or deaths associated with unsafe dietary supplements.

G. What Requirements Apply to Filling, Assembling, Packaging, Labeling, and Related Operations? (Final § 111.415)

Final § 111.415 requires that you fill, assemble, package, label, and perform other related operations in a way that ensures the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. Final § 111.415 also requires that you do these functions using any effective means you choose, including: (1) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary supplement packaging, as appropriate; (2) protecting manufactured dietary supplements from contamination, particularly airborne contamination; (3) using sanitary handling procedures; (4) establishing physical or spatial separation of packaging and label operations from operations on other components and dietary supplements to prevent mixups; (5) identifying, by any effective means, filled dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups; (6) assigning a batch, lot, or control number to each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement and each lot of dietary supplement from a finished batch of dietary supplement that you distribute to another person for packaging or labeling; (7) examining a representative sample of each batch of the packaged and labeled dietary supplement to determine whether the dietary supplement meets specifications established in accordance with final § 111.70(g); and (8) suitably disposing of labels and packaging for dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and labeling operations.

Final § 111.415 derives from proposed § 111.70(b). We revised the section to be consistent with other revisions.

(Comment 304) Some comments request clarification as to what specifications we are referring to in proposed § 111.70(b)(7). The comments state that if we are referring to specifications required by proposed § 111.35(e), then we should indicate so in any final rule. The comment asserts that, if we intend this provision to mean that persons who simply package, label, and store dietary supplements must conduct full product testing, then proposed § 111.70(b)(7) is unwarranted and unreasonable.

The comments assert that full product testing should not be required for companies that merely package, label, and store finished products. The comments assert that in-route contamination from the facility of a supplier or manufacturer to the facility of a packager, labeler, or distributor facility is unlikely to occur if the proper environmental conditions are maintained as required by other provisions of the 2003 CGMP Proposal. The comments assert that the responsibility for raw material and finished product testing should lie solely with the companies that handle the raw materials and dietary ingredients and that perform manufacturing duties. According to the comments, assuming the supplier/manufacturer complies with the final rule and adequately performs the required testing, reasonable cost/benefit analysis would dictate that redundant testing not be performed. Therefore, the comments assert that those who perform packaging and labeling operations should only be required to test those areas of contamination that are likely to occur during the shipment, or in the receipt, identification, packaging, and holding areas of production operations (e.g., surface contamination).

The comments state it is our duty to ensure that the industry is complying with any final rule, not the duty of certain segments of the industry to ensure that other segments of the industry are complying. Since in-route contamination is unlikely and rare, consumers would enjoy little or no benefit from redundant testing at a tremendous cost to the industry, particularly small businesses.

(Response) The term ''specifications'' in proposed § 111.70(b)(7) included any specifications that you established for packaged and labeled dietary supplements under proposed § 111.35(e). In final § 111.415(g), we identify the specifications as those you establish in accordance with final § 111.70(g). In final § 111.70(g), we require you to establish specifications for the packaging and labeling for the finished packaged and labeled dietary supplements. We distinguish these specifications (final § 111.70(g)) from product specifications you must establish for a finished batch that you manufacture (final § 111.70(e)). The specifications that you establish and follow ensure that your product is what you establish in your master manufacturing record. As discussed in sections VI and section XII of this document, a master manufacturing record for a firm that only packages and labels the dietary supplement would include specifications that are applicable to its operations and would not include specifications related to, for example, components.

H. What Requirements Apply to Repackaging and Relabeling? (Final § 111.420)

1. Final § 111.420(a)

Final § 111.420(a) provides that you may repackage or relabel dietary supplements only after your quality control personnel have approved such repackaging or relabeling. Final § 111.420(a) is similar to proposed § 111.70(d) with a restructuring of the provision for clarity. We did not receive comments specific to proposed § 111.70(d).

2. Final § 111.420(b) and (c)

Final § 111.420(b) requires you to examine a representative sample of each batch of repackaged or relabeled dietary supplements to determine whether the repackaged or relabeled dietary supplements meet all specifications established in accordance with § 111.70(g). Final § 111.420(c) requires that quality control personnel approve or reject each batch of repackaged or relabeled dietary supplement prior to its release for distribution. Final § 111.420(b) and (c) derive from proposed § 111.70(e) which would require you to retest or re-examine any repackaged or relabeled dietary supplements. Proposed § 111.70(e) also would require that any repackaged or relabeled dietary supplements meet all specifications and that the quality control unit approve or reject their release for distribution.

(Comment 305) Some comments assert that the proposed requirement that directs companies to retest or re-examine any repackaged or relabeled dietary supplement unnecessarily restricts the ability of the quality control unit to make an appropriate disposition decision. These comments assert that testing would not be necessary, for example, when a packager repackages a multiple vitamin softgel from a 500-count bottle to a 60-count bottle. The comments also assert that it would be costly to retest such product, and that such testing would not benefit consumer health and safety. The comments would revise proposed § 111.70(e) to give the quality control unit the authority to make an appropriate disposition decision, e.g., to assess the repackaged dietary supplement for conformity to specifications.

(Response) We agree that there are circumstances, such as those described by these comments, when testing would not be necessary. However, we disagree that it would not be necessary to ''examine'' a representative sample of the repackaged and relabeled dietary supplement to determine whether the required specifications are met, i.e., that you used the specified packaging and applied the specified label. If no examination of a representative sample took place, there would be no basis for the determination. We believe that final § 111.420(b) makes this clear.

I. What Requirements Apply to a Packaged and Labeled Dietary Supplement That Is Rejected for Distribution? (Final § 111.425)

Final § 111.425 requires you to clearly identify, hold, and control under a quarantine system for appropriate disposition any packaged and labeled dietary supplement that is rejected for distribution. Final § 111.425 derives from proposed § 111.74 which would require you to clearly identify, hold, and control under a quarantine system any component, dietary ingredient, dietary supplement, packaging, and label that is rejected and unsuitable for use in manufacturing, packaging, or label operations. Under the final rule, the requirements of proposed § 111.74 for components, packaging, and labels are being set forth in final § 111.170, and the requirements for a finished batch of dietary supplement are set forth in final § 111.370. Although the proposal did not include any packaged and labeled dietary supplement rejected for distribution, we are making this change to be consistent with the principle that rejected components, dietary supplements, packaging, or labels unsuitable for the distribution supply include finished product already packaged and labeled.

J. Under This Subpart, What Records Must You Make and Keep? (Final § 111.430)

1. Final § 111.430(a)

Final § 111.430(a) requires you to make and keep records required under this subpart in accordance with subpart P. Final § 111.430(a) derives from proposed § 111.70(h) with revisions associated with the reorganization. We did not receive comments specific to proposed § 111.70(h).

2. Final § 111.430(b)

As discussed in this section, final § 111.403 requires you to establish and follow written procedures for packaging and labeling operations. The written procedures are records. Therefore, final § 111.430(b) requires you to make and keep records of the written procedures for packaging and labeling operations.

XVIII. Comments on Holding and Distributing (Final Subpart M)

A. Organization of Final Subpart M

In the 2003 CGMP Proposal, the requirements for holding operations were set forth in §§ 111.80, 111.82, and 111.83 in subpart F; the requirements for distribution operations were set forth in proposed § 111.90 in subpart F. As shown in table 14 of this document, the final rule moves the requirements related to holding and distributing operations to a new subpart (final Subpart M—Holding and Distributing). Table 14 lists the sections in the final rule and identifies the sections that form the basis of the final rule.

TABLE 14.—DERIVATION OF SECTIONS IN FINAL SUBPART M

Final Rule	2003 CGMP Proposal
§ 111.453 What are the requirements under this subpart M for written procedures?	N/A
§ 111.455 What requirements apply to holding components, dietary supplements, packaging, and labels?	§ 111.80
§ 111.460 What requirements apply to holding in-process material?	§ 111.82
§ 111.465 What requirements apply to holding reserve samples of dietary supplements?	§ 111.83(b)(1) and (b)(2)
§ 111.470 What requirements apply to distributing dietary supplements?	§ 111.90
§ 111.475 Under this subpart M, what records must you make and keep?	N/A

B. Highlights of Changes to the Proposed Requirements for Holding and Distributing

1. Revisions

The final rule includes changes that reflect that the scope of the final rule applies to persons who manufacture, package, label, or hold dietary supplements, unless subject to an exclusion in § 111.1.

2. Changes Associated With the Reorganization

Final § 111.465 in subpart M duplicates the requirement of final § 111.83(b)(3) to retain reserve samples of dietary supplements for 1 year past the shelf life date (if shelf life dating is used) or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples. We are duplicating this requirement in this subpart because we believe that it will be useful to include the length of time that you must hold reserve samples in each place of the codified where it is logical to look for this information.

3. Changes After Considering Comments

The final rule:

- Does not require that you collect reserve samples of components;
- Provides flexibility as to the container-closure system used to hold reserve samples of dietary supplements;
- Includes a new requirement for written procedures; and
- Includes a new requirement to make and keep records of product distribution and written procedures.

C. General Comments on Proposed §§ 111.80, 111.82, 111.83, and 111.85

(Comment 306) One comment requests that factory sealed finished products, which have been specifically manufactured to be held and transported in a variety of conditions, be excluded from the requirements for holding. Another comment states that there are many types of companies or individuals in the supply chain who may ''hold'' a dietary supplement after final production, packaging, and labeling is complete. This comment seeks clarification that brokers, distributors, or wholesalers would be subject only to the proposed requirements for holding in proposed § 111.90.

(Response) If you hold a dietary supplement, you are subject to all applicable requirements of these CGMP regulations related to your operation. For example, if you are a wholesaler, you would be subject to the requirements in final § 111.470 for the dietary supplements you are holding for distribution as well as other applicable requirements, such as those related to personnel, physical plant and grounds, equipment and utensils, quality control, returned dietary supplements, and product complaints. We decline to list all of the requirements that would be applicable because individual operations may vary. However, we provide the following examples of

requirements that would, or would not, apply in some specific circumstances. For example, if the dietary supplements that you hold require refrigeration, your refrigeration equipment must comply with the requirements to be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that shows the temperature accurately within the compartment, and have an automated device for regulating temperature or an automatic alarm system to indicate a significant temperature change in a manual operation. However, you would not be required to establish specifications for the finished batch of the dietary supplement, for product that is received for packaging or labeling, or for packaged and labeled dietary supplements or to determine whether such specifications are met if you only hold the product and do not perform any other functions.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.453)

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section.

We are including a new provision, § 111.453 ''What are the requirements under this subpart M for written procedures?'' which requires you to establish and follow written procedures for holding and distribution operations.

E. What Requirements Apply to Holding Components, Dietary Supplements, Packaging, and Labels? (Final § 111.455)

1. Final § 111.455(a)

Final § 111.455(a) requires you to hold components and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and dietary supplements are not affected. Final § 111.455(a) derives from proposed § 111.80(a) which would require that you hold components, dietary ingredients, and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, quality, strength, and composition of the components, dietary ingredients, and dietary supplements are not affected.

We did not receive comments specific to proposed § 111.80(a).

2. Final § 111.455(b)

Final § 111.455(b) requires you to hold packaging and labels under appropriate conditions so that the packaging and labels are not adversely affected. Final § 111.455(b) derives from proposed § 111.80(b) with modifications for consistency with other provisions addressing packaging and labels.

We did not receive comments specific to proposed § 111.80(b).

3. Final § 111.455(c)

Final § 111.455(c) requires you to hold components, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary supplements, packaging, and labels. Final § 111.455(c) derives from proposed § 111.80(c).

We did not receive comments specific to proposed § 111.80(c).

F. What Requirements Apply to Holding In-Process Material? (Final § 111.460)

1. Final § 111.460(a)

Final § 111.460(a) requires you to identify and hold in-process material under conditions that protect against mixups, contamination, and deterioration. Final § 111.460(a) is similar to proposed § 111.82(a) with a grammatical change (i.e., a change from ''that will protect them'' to ''that protect'').

We did not receive comments specific to proposed § 111.82(a).

2. Final § 111.460(b)

Final § 111.460(b) requires you to hold in-process material under appropriate conditions of temperature, humidity, and light. Final § 111.460(b) is identical to proposed § 111.82(b).

(Comment 307) One comment asserts it would be impractical, unnecessary, and extremely burdensome to maintain reserve samples of in-process materials. The comment asserts that collecting and holding samples of in-process materials would duplicate the requirement to collect and hold reserve samples of finished dietary supplements and require significant additional documentation, time, and storage space.

(Response) This comment may have misinterpreted proposed § 111.37(b)(11) (final §111.80(g)) which included requirements for collecting representative, rather than reserve, samples of in-process materials. The representative sample is used for those tests or examinations conducted to determine whether the batch meets specifications. A representative sample is held for only a short period of time, i.e., the time between the collection and the test or examination. Neither the 2003 CGMP Proposal nor this final rule includes a requirement to maintain a reserve sample of in-process materials.

G. Proposed Requirement for Holding Reserve Samples of Components (Proposed § 111.83(a))

Proposed § 111.83(a) would require you to hold any collected reserve samples of components or dietary ingredients in a manner that protects against contamination and deterioration.

(Comment 308) One comment requests the final rule not require that manufacturers of dietary supplements collect and hold reserve samples of components. The comment asserts that all components can be traced back to their source (i.e., the vendor or manufacturer of the material) for a more in-depth investigation if a dietary supplement comes under investigation due to a product complaint.

(Response) We agree with this comment. Therefore, the final rule contains no requirement for holding reserve samples of components, only finished dietary supplements, and, thus, proposed § 111.83(a) has no counterpart in the final rule.

H. What Requirements Apply to Holding Reserve Samples of Dietary Supplements? (Final § 111.465)

1. Final § 111.465(a)

Final § 111.465(a) requires you to hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. Under final § 111.465(a)(1) this includes holding the reserve sample under conditions consistent with product labels or, if no storage conditions are recommended on the label, under ordinary storage conditions. Final § 111.465(a)(1) derives from proposed § 111.83(b)(1) which would require you to hold reserve samples under conditions of use recommended or suggested in the label of the dietary supplement and, if no conditions of use are recommended or suggested in the label, then under ordinary conditions of use.

Final § 111.465(a)(1) refers to ''conditions consistent with product labels'' rather than to ''conditions of use recommended or suggested in the label of the dietary supplement'' and refers to ''storage conditions'' rather than ''conditions of use.'' This change is to reflect that the ''conditions of use'' referenced in the 2003 CGMP Proposal referred to the typical storage of the dietary supplement and not the consumption of the product by the consumer.

We did not receive comments specific to proposed § 111.83(b)(1).

Under final § 111.465(a)(2) the manner in which you hold reserve samples of dietary supplements

includes using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which you distribute the dietary supplement for packaging and labeling elsewhere. Final § 111.465(a)(2) derives from proposed § 111.83(b)(2) which would require that the manner in which you hold reserve samples of dietary supplements include using the same container-closure system in which the dietary supplement is marketed or in one that provides the same level of protection against contamination or deterioration.

(Comment 309) One comment states a substantial amount of its product is shipped in bulk for packaging elsewhere. As a result, one often does not know the packaging being used to market the dietary supplement or how the packaged product is being stored. This comment recommends we revise the proposed regulation to require using the same container-closure system in which the dietary supplement is marketed ''if known and if not in a typical market container-closure system.''

(Response) We acknowledge that some manufacturers of dietary supplements will distribute product in bulk and will not know the packaging used to market the dietary supplement. In addition, if you ship products in bulk, any commitment you make to your customer about the quality of the product you shipped would relate to the container you used to ship the bulk product. To address these points we provide in final § 111.465(a)(2) that you have the flexibility to use a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which it is distributed for packaging and labeling elsewhere. For example, if you distribute product in bulk using a polyethylene bottle that can hold 50 kilograms of the product, and there is an air space above the product, you would hold the reserve samples in a polyethylene bottle with an air space. However, you would use a bottle that is sized to fit the amount that you are holding in reserve.

2. Final § 111.465(b)

Final § 111.465(b) requires you to retain reserve samples for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples, for use in appropriate investigations. Final § 111.465(b) derives from proposed § 111.37(b)(12), which proposed, in part, that you must keep reserve samples for 3 years from the date of manufacture. Proposed § 111.37(b)(12) is now final § 111.83(b)(3) with a change to 2 years for the retention period and with changes that we are making consistent with comments that requested that the time frame for retaining reserve samples be linked to a shelf life date (or other form of expiration dating) when such a date is established. We discuss the reasons for the change from 3 years to 2 years and the change from ''date of manufacture'' to ''the date of distribution'' in section XXI of this document. In essence, final § 111.465(b) duplicates final § 111.83(b)(3) because we believe it will be useful to include the length of time you must hold reserve samples in each place in the codified where it is logical to look for this information.

I. What Requirements Apply to Distributing Dietary Supplements? (Final § 111.470)

Final § 111.470 requires you to distribute dietary supplements under conditions that will protect the dietary supplements against contamination and deterioration. Final § 111.470 derives from proposed § 111.90.

We did not receive comments specific to proposed § 111.90.

J. Under This Subpart, What Records Must You Make and Keep? (Final § 111.475)

In the 2003 CGMP Proposal, we invited comment on whether we should require you to make and keep records on the distribution of dietary supplements that you manufacture, package, or hold.

(Comment 310) Some comments assert that written records of product distribution would provide the ability to trace the shipment of each finished batch in the event of a product recall. One comment expresses the view that the ability to quickly and efficiently recall a product is an important safeguard in ensuring public health in the event of a serious problem. Another comment points out that the scope of recall would likely be much broader if records of product distribution were not available to pinpoint distribution.

(Response) We agree with these comments. Therefore, final § 111.475 requires you to make and keep records of product distribution in accordance with subpart P. In addition, we are adding a provision to complement final § 111.453 to ensure that records are maintained of the written procedures you establish for holding and distributing operations. As discussed, comments stressed that such procedures must be available to us during the course of an inspection.

(Comment 311) One comment asserts that the final rule should not include a requirement for records of product distribution, because such records are already common industry practice. This comment also points out that neither the food CGMPs in part 110 nor the agency's 1997 ANPRM have requirements for records of product distribution.

(Response) To the extent that the comment asserts that a practice that is a common industry practice should not be a requirement in the final rule, we disagree. CGMP includes those practices that may be commonly used in industry. In fact, the reason that such practices may be common in industry is because they are already considered to be CGMP. As we noted in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12221), however, not all dietary supplement establishments follow CGMP and, therefore, may not be keeping records of product distribution. Thus, in this final rule we do not exclude practices we consider to be CGMP and already may be used by some in industry.

The industry outline we published in the 1997 ANPR suggested (under Warehousing, Distribution, and Post-Distribution Procedures) that the CGMP rule require adequate distribution records to be maintained and retained for at least 1 year beyond the expected product shelf life, whereby an effective product recall can be achieved should one become necessary. Therefore, we disagree that the 1997 ANPRM did not suggest a requirement to make and retain records of product distribution.

XIX. Comments on Returned Dietary Supplements (Final Subpart N)

A. Organization of Final Subpart N

In the 2003 CGMP Proposal, the requirements for returned dietary supplements were set forth in proposed § 111.85. As shown in table 15 of this document, we are reorganizing proposed § 111.85 into a distinct subpart (final Subpart N—Returned Dietary Supplements). Table 15 lists the sections in final subpart N and identifies the proposed sections that form the basis of the final rule.

TABLE 15.—DERIVATION OF SECTIONS IN FINAL SUBPART N

Final Rule	2003 CGMP Proposal
§ 111.503 What are the requirements under this subpart N for written procedures?	N/A
§ 111.510 What requirements apply when a returned dietary supplement is received?	§ 111.85(a)
§ 111.515 When must a returned dietary supplement be destroyed, or otherwise suitably disposed of?	§ 111.85(b) and (c)
§ 111.520 When may a returned dietary supplement be salvaged?	§ 111.37(b)(15)
§ 111.525 What requirements apply to a returned dietary supplement that quality control personnel approve for reprocessing?	§ 111.50(g)
§ 111.530 When must an investigation be conducted of your manufacturing processes and other batches?	§ 111.85(d)
§ 111.535 Under this subpart N, what records must you make and keep?	§ 111.50(g) § 111.85(e) and (f)

B. Highlights of Changes to the Proposed Requirements for Returned Dietary Supplements

1. Revisions

The final rule includes:

- Revisions that reflect that the final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.
- A provision (final § 111.520) that we are adding for consistency, so that the final rule for returned dietary supplements clearly sets forth the requirements for a positive outcome (i.e., when you may salvage a returned dietary supplement) as well as a negative outcome (i.e., when you must destroy or otherwise suitably dispose of a returned dietary supplement); and
- A provision (final § 111.525) we are adding for consistency, so that the final rule for returned dietary supplements clearly sets forth the requirements for reprocessed materials.

2. Changes After Considering Comments

The final rule:

- Includes a new requirement to establish and follow written procedures to fulfill the requirements for returned dietary supplements;
- Includes a revised description of the conditions that preclude you from salvaging a returned dietary supplement; and
- Provides flexibility for firms to salvage a returned dietary supplement without conducting tests to demonstrate that the dietary supplement meets all specifications, provided that quality control personnel conduct a material review and make a disposition decision to approve the salvage.

C. General Comments on Proposed § 111.85

(Comment 312) Several comments request we clarify the roles of the various parties in the ''pre-consumer supply chain'' for dietary supplements.

(Response) We have discussed, in section VI of this document, who is subject to the final rule in what the comment describes as the ''pre-consumer supply chain'' and do not repeat that discussion here. The requirements for returned dietary supplements do not distinguish between those returned to a person who manufactures a finished batch and those returned to a person whose role in the manufacturing process is limited to operations such as packaging, labeling, or holding.

Any reprocessing operations, other than repackaging or relabeling, by a packager or labeler who receives a product for packaging or labeling as a dietary supplement would make that packager or labeler subject to all relevant regulatory requirements under this final rule, as explained in section VI of this document. A packager or labeler that only conducts repackaging or relabeling operations may conclude that a product was returned for reasons related to a problem with the manufacture of the product it received for packaging or labeling, and therefore cannot be salvaged. In such a case, under final § 111.515 the packager or labeler would have to destroy or otherwise suitably dispose of the dietary supplement. Under final § 111.515, the packager or labeler may contact the manufacturer to determine if the packager or labeler could suitably dispose of the dietary supplement by sending it back to the manufacturer for possible reprocessing (see discussion of final § 111.515 in this section). A manufacturer who receives a dietary supplement returned by a packager or labeler would be required to comply with the requirements of final subpart N for returned dietary supplements, including requirements for any reprocessing of the returned dietary supplements.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.503)

We received many comments that recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section.

Final § 111.503 requires you to establish and follow written procedures to fulfill the requirements of subpart N. Under final § 111.535(b)(1) we are requiring you to make and keep records of such written procedures. Such records would be available to us under the requirements in subpart P.

E. What Requirements Apply When a Returned Dietary Supplement is Received? (Final § 111.510)

Final § 111.510 requires you to identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision. Final § 111.510 is similar to proposed § 111.85(a).

We did not receive comments specific to proposed § 111.85(a).

F. When Must a Returned Dietary Supplement Be Destroyed, or Otherwise Suitably Disposed Of? (Final § 111.515)

Final § 111.515(a) requires that you destroy, or otherwise suitably dispose of, any returned dietary supplement, unless the outcome of a material review and disposition decision is that quality control personnel either: (1) Approve the salvage of the returned dietary supplement for redistribution or (2) approve the returned dietary supplement for reprocessing. Final § 111.515(a) derives from the following proposed sections:

- Proposed § 111.85(b) which would require that you not salvage returned dietary supplements unless: (1) Evidence from their packaging (or, if possible, an inspection of the premises where the dietary ingredients and dietary supplements were held) indicates that the dietary ingredients and dietary supplements were not subjected to improper storage conditions and (2) tests demonstrate that the dietary ingredients or dietary supplements meet all specifications for identity, purity, quality, strength, and composition; and
- Proposed § 111.85(c) which would require that you destroy or suitably dispose of the returned dietary

ingredients or dietary supplements if such dietary ingredients and dietary supplements do not meet specifications, unless the quality control unit conducts a material review and makes a disposition decision to allow reprocessing.

Final § 111.515(a) includes editorial changes and other changes made after considering comments.

(Comment 313) Several comments assert it is unnecessary to conduct testing for all specifications for every returned product because products may be returned for reasons unrelated to product quality. For example, products may be returned due to overstocking, ordering the wrong quantity, going out of business, or failing to pay for the product on time. In addition, several comments assert that many returned products are intact, show no signs of mishandling, and are within the time limits for shelf life. These comments assert that a material review and disposition decision by the quality control unit to restock the material without retesting may be acceptable in these types of situations. Some comments assert that proposed § 111.85(b) is more restrictive than CGMP requirements for drug products, and suggest that testing need be conducted only when some doubt has been cast upon the identity, purity, quality, strength, or composition of the product, or if the product was returned for some other GMP-related problem.

Some comments contend that proposed §§ 111.35(i)(3)(v) and 111.85 would make it difficult to salvage any returned product because companies receiving returns often cannot verify the conditions under which such products were held. One comment refers to a stakeholder meeting when we indicated that the extent of testing requirements would depend upon the reason such products were returned. The comments state that the rule should allow flexibility as to when returned products must be tested.

Some comments specifically suggest the approach used in the USP (revised in 2nd supplement USP 26). These comments suggest that proposed § 111.85(b) be revised as follows: ''If the conditions under which returned products have been held, stored, or shipped before or during their return, or if the condition of the product, its container, carton or labeling, as a result of storage or shipping, cast doubt on the safety, identity, strength, quality, or purity of the product, the returned product should be destroyed unless examination, testing or other investigations prove the product meets appropriate standards of safety, identity, strength, quality, or purity.''

These comments assert that inspection of the condition of the returned product could be used to determine that a product can be returned to inventory, and this inspection could be covered by internal procedures and based on experience in testing product stored under conditions that include extremes in heat and humidity without affecting the container or closure system.

(Response) As already discussed in this section, the final rule includes a new requirement that you establish and follow written procedures for handling returned dietary supplements. The final rule also retains the requirement that quality control personnel (formerly ''unit'' in the proposed rule) conduct a material review and make a disposition decision regarding all returned dietary supplements (see discussion of final § 111.113(a)(5) in section XI of this document). We agree with the comments that it is not necessary to conduct testing for all specifications for every returned product, because products may be returned for reasons unrelated to the quality of the dietary supplement. Final § 111.130 provides for quality control personnel to determine whether tests or examinations are necessary for returned dietary supplements to determine compliance with product specifications. Therefore, final § 111.515 does not include a testing requirement. We believe the combination of written procedures and oversight by quality control personnel is adequate to determine the appropriate disposition of a returned dietary supplement, without requiring a test in every case to demonstrate that the dietary supplement meets specifications for identity, purity, strength, and composition.

In final § 111.515(a) we generally accept the comments' suggestions and reflect the approach of the USP for returned products. Thus, you must destroy or otherwise suitably dispose of the returned dietary supplement, unless the outcome of the material review and disposition decision is that quality control personnel approve the salvage of the returned dietary supplement for redistribution or approve the reprocessing of the returned dietary supplement. We provide flexibility on how quality control personnel may conduct a material review and make a disposition decision and do not require testing in every case. We respond in section V of this document to the comment asserting that the proposed CGMPs exceed the drug CGMPs.

G. When May a Returned Dietary Supplement Be Salvaged? (Final § 111.520)

Final § 111.520 permits the salvage of a returned dietary supplement only if quality control personnel conduct a material review and make a disposition decision to allow the salvage. Final § 111.520 is a conforming provision we are adding for consistency, so that the final requirement for returned dietary supplements clearly sets forth a positive outcome (i.e., when you may salvage a returned dietary supplement) as well as a negative outcome (i.e., when you must destroy or otherwise suitably dispose of a returned dietary supplement). Final § 111.520 is consistent with final § 111.130 (proposed § 111.37(b)(15)) which requires quality control personnel to approve the distribution of returned dietary supplements.

H. What Requirements Apply to a Returned Dietary Supplement That Quality Control Personnel Approve for Reprocessing? (Final § 111.525)

Final § 111.525(a) requires you to ensure that any returned dietary supplements that are reprocessed meet all product specifications established in accordance with final § 111.70(e). Final § 111.525(b) requires quality control personnel to approve or reject the release for distribution of any returned dietary supplement that is reprocessed. As with final § 111.520, final § 111.525 is a provision we are adding for consistency. Final § 111.525 is consistent with final § 111.90(c).

I. When Must an Investigation Be Conducted of Your Manufacturing Processes and Other Batches? (Final § 111.530)

Final § 111.530 requires that, if the reason for a dietary supplement being returned implicates other batches, you must conduct an investigation of your manufacturing processes and each of those other batches to determine compliance with specifications. Final § 111.530 derives from proposed § 111.85(d) which would require that if the reason for a dietary supplement being returned implicates associated batches, you must conduct an investigation of your manufacturing processes and those other batches to determine compliance with specifications. Final § 111.530 includes a nonsubstantive editorial change of ''associated'' to ''each of those other batches'' for clarity.

We did not receive comments specific to proposed § 111.85(d).

J. Under This Subpart, What Records Must You Make and Keep? (Final § 111.535)

Final § 111.535 sets forth the requirements to make and keep records for returned dietary supplements. Final § 111.180 derives from proposed § 111.85(e) and (f).

We did not receive comments specific to proposed § 111.85(e) or (f).

1. Final § 111.535(a)

Final § 111.535(a) requires you to make and keep records required under subpart N in accordance with subpart P. Final § 111.535(a) derives from proposed §111.85(f) and includes changes associated with the reorganization.

2. Final § 111.535(b)(1)

As discussed in this section, the final rule includes a new requirement (final § 111.503) that you establish and follow written procedures to fulfill the requirements of subpart N. Those written procedures are records. Therefore, final § 111.535(b)(1) requires you to make and keep a record of the written procedures for fulfilling the requirements of subpart N.

3. Final § 111.535(b)(2)

Final § 111.535(b)(2) requires you to make and keep a record of any material review and disposition decision on a returned dietary supplement. Final § 111.535(b) derives from proposed § 111.85(e), with revisions associated with the reorganization.

4. Final § 111.535(b)(3)

Final § 111.535(b)(3) requires you to make and keep a record of the results of any testing or examination conducted to determine compliance with product specifications established under § 111.70(e). Final § 111.535(b) derives from proposed § 111.85(e) which would require you to establish and keep records on any testing conducted to determine compliance with established specifications in the master manufacturing record for the type of dietary supplement that was returned. Final § 111.535(b)(3) includes the following revisions:

- Consistent with final § 111.70(e), final § 111.535(b)(3) substitutes ''product specifications established under § 111.70(e)'' for ''established specifications in the master manufacturing record for the type of dietary ingredient or dietary supplement that was returned.''
- Consistent with final § 111.75(c), final § 111.535(b)(3) provides flexibility to use either tests or examinations to determine whether specifications are met.

5. Final § 111.535(b)(4)

Final § 111.535(b)(4) requires you to make and keep a record of documentation of the re-evaluation by quality control personnel of any dietary supplement that is reprocessed and the determination by quality control personnel of whether the reprocessed dietary supplement meets product specifications established in accordance with § 111.70(e). Final § 111.535(b)(4) is related to final § 111.525. Under final § 111.525, you must ensure that any returned dietary supplements that are reprocessed meet all product specifications you established under § 111.70(e) and quality control personnel must approve or reject the release for distribution of any returned dietary supplement that is reprocessed.

XX. Comments on Product Complaints (Final Subpart O)

A. Organization of Final Subpart O

In the 2003 CGMP Proposal, the requirements for consumer complaints were set forth in § 111.95. As shown in table 16 of this document, we are reorganizing proposed § 111.95 into three provisions in a new subpart (final Subpart O—Product Complaints). Table 16 lists the sections in final subpart O and identifies the provisions that form the basis for the final rule.

TABLE 16.—DERIVATION OF SECTIONS IN FINAL SUBPART O

Final Rule	2003 CGMP Proposal
§ 111.553 What are the requirements under this subpart O for written procedures?	N/A
§ 111.560 What requirements apply to the review and investigation of a product complaint?	§ 111.95(a), (b), (c), and (d)
§ 111.570 Under this subpart O, what records must you make and keep?	§ 111.95(e) and (f)

B. Highlights of Changes to the Proposed Requirements for Product Complaints

1. Revisions

The final rule:

- Includes changes that reflect the final rule applies to persons who manufacture, package, label, or hold dietary supplements unless subject to an exclusion in § 111.1.
- Uses the term ''product complaint'' rather than ''consumer complaint,'' and the definition of ''product complaint'' does not include an explanation about the types of complaints that may or may not be covered by the CGMP regulations. The definition does, however, include examples of product complaints.

2. Changes After Considering Comments

The final rule modifies the process for handling product complaints as follows:

- A qualified person investigates any product complaint that involves a possible failure of a dietary supplement to meet any requirements of part 111, without an intermediate step of having quality control personnel first determine whether the complaint should be investigated;
- Quality control personnel review and approve all decisions made by a qualified person about whether to investigate a product complaint and the findings and followup action of any investigation performed rather than conduct the investigation and followup; and
- The review and investigation of the product complaint extends to all relevant batches and records, without identifying specific records, and specific batches, that must be included in the review and investigation.

C. General Comments on Proposed § 111.95 (Final Subpart O)

(Comment 314) Some comments express general support for the proposed procedures for consumer complaints. Other comments request proposed § 111.95 be deleted. Most of these comments point out that we had announced the development of CFSAN's Adverse Event Reporting System (CAERS) for reporting to FDA adverse events attributed to food products and suggest that this new system would be the appropriate mechanism for handling complaints about dietary supplements.

(Response) We disagree with these comments. Because the problem giving rise to the complaint may be associated with a failure in manufacturing, packaging, labeling, or holding, it is CGMP for a firm that receives a product complaint to review it and investigate, if necessary, regardless of whether we are notified about the complaint. An important goal of the firm's review and investigation is to determine whether there is a problem with the production and process control system for the manufacture, packaging, labeling, or holding of the dietary supplement. That

goal would not be achieved merely by notifying us. A firm subject to any of the requirements of this final rule, whether such firm is a manufacturer, packager, labeler, or holder, is responsible for the requirements in subpart O for a product complaint it receives.

(Comment 315) Some comments assert that the proposed requirements for consumer complaints do not go far enough and urge that any final rule require any complaints that involve an adverse event be referred to us. The comments stress accurate reporting of adverse events is essential to long term evaluations of a product's safety.

(Response) Mandatory reporting requirements to us regarding adverse events related to dietary supplements are outside the scope of this rulemaking. This final rule addresses the internal processes and controls that persons who manufacture, package, label, or hold dietary supplements must follow. Mandatory reporting to FDA of serious adverse events, however, is now required as a result of the enactment of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462) signed into law on December 22, 2006. The new law requires manufacturers, packers, or distributors of such products to submit reports to FDA about serious adverse events involving such products based on specific information that they receive from the public. Serious adverse events are defined in the law as those events that result in death, a life-threatening situation, an inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect or one that requires medical or surgical intervention to prevent such serious outcomes (based on reasonable medical judgment).

As discussed in the preamble to the 2003 CGMP Proposal (68 FR 12157 at 12217), however, we continue to strongly recommend that firms that receive product complaints, that are not ''serious adverse events,'' notify us about any illness or injury, because, for example, we may have additional expertise or data that may be helpful in investigating the complaint or determining whether the problem applies to more than one product. In light of the requirement in the final rule to establish and follow written procedures for handling product complaints, we encourage you to include our recommendations in the written procedures that you develop for handling product complaints (see discussion of final § 111.553 in this section).

(Comment 316) Some comments raise questions about who would be subject to the proposed requirements regarding consumer complaints. Some comments state the section should apply only to manufacturers of dietary supplements, not to manufacturers of dietary ingredients. Other comments are concerned that distributors who merely put their label on the finished product may be held responsible for keeping records of adverse events caused by failures to follow CGMPs during the manufacture of the supplements.

(Response) The final rule only applies to persons who manufacture, package, label, or hold a dietary supplement. We discuss the scope of this final rule in detail in section VI of this document.

In most cases, the person who receives a product complaint from a consumer will be the manufacturer, packager, or distributor of the dietary supplement. A distributor (also a ''holder'' under this final rule) who receives a product complaint must review and investigate that complaint to determine whether the complaint relates to a failure of the processes under the control of the distributor, such as conditions of temperature, humidity, and light that could affect the identity, purity, strength, or composition of the dietary supplement. If the distributor concludes the problem is unrelated to any process under the control of the distributor, the distributor should contact the manufacturer. Under the final rule, any person in the manufacturing chain who receives a product complaint—regardless of the source—must comply with the requirements in this subpart O.

(Comment 317) One comment suggests proposed § 111.95, which describes requirements for consumer complaints, could be combined with proposed § 111.85 which describes requirements for returned dietary supplements.

(Response) We decline to adopt this suggestion. In this final rule, we are incorporating the requirements for returned dietary supplements into a distinct subpart (final subpart N) that sets forth requirements for returned dietary supplements. The procedures described in final subpart O, which relate solely to the handling of product complaints rather than returned dietary supplement products, are quite different from those described in final subpart N, which addresses the handling, review, and possible reprocessing of returned product.

(Comment 318) Some comments assert the proposed requirements for complaints are different from those for food CGMPs.

(Response) We are making no changes to the requirements after considering these comments. We responded in section V of this document to similar comments asserting that certain aspects of the proposed regulations are different from those for other food CGMP requirements.

D. What Are the Requirements Under This Subpart for Written Procedures? (Final § 111.553)

We received many comments which recommended written procedures for various provisions. We address the need for written procedures generally in section IV of this document. We also respond to individual comments on specific provisions in the same section.

Final § 111.553 requires that you establish and follow written procedures to fulfill the requirements of this subpart O. Under final § 111.570(b)(1) we require you to make and keep records of such procedures. Such records would be required to be made available to us under the requirements in subpart P.

We encourage you to include in your written procedures the recommendation made in the 2003 CGMP Proposal for you to consult with a health care provider if you receive complaints that involve serious illness or injury. Even if the complaints are not required to be submitted to FDA under the newly enacted ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), we encourage your company to notify us about the product complaints. Manufacturers and distributors should be aware that this newly enacted law, which requires reporting to FDA of ''serious adverse events,'' contains new mandatory provisions that require record retention of adverse event reports separate from the requirements in this CGMP final rule concerning product complaints.

E. What Requirements Apply to the Review and Investigation of a Product Complaint? (Final § 111.560)

1. Final § 111.560(a)(1)

Final § 111.560(a)(1) requires a qualified person to review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of part 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury. Final § 111.560(a)(1) derives from proposed § 111.95(a).

We did not receive comments specific to proposed § 111.95(a).

2. Final § 111.560(a)(2), (b), and (c)

Final § 111.560(a)(2) requires a qualified person to investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of part 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury. Final § 111.560(b) requires that quality control personnel review and approve decisions by the qualified person about whether or not to investigate a product complaint and the findings and followup action of any investigation performed. Final § 111.560(c) requires that the review and investigation extend to all relevant batches and records.

(Comment 319) Some comments characterize the requirements of proposed § 111.95 as a confusing and difficult scheme to review, investigate, and resolve customer complaints. These comments state the 2003 CGMP Proposal would require extensive human resources, recordkeeping, and decisionmaking.

(Response) We disagree that the 2003 CGMP Proposal would require extensive human resources, recordkeeping, or decisionmaking. The comments provided no rationale for such assertions. The 2003 CGMP Proposal sets forth basic steps, i.e., review, evaluation, and followup, that one would need to take to appropriately address a product complaint. For those product complaints for which there is a reasonable possibility of a relationship to an adverse event, the 2003 CGMP Proposal would require that an investigation be done by the quality control unit because we believe such an event would need more careful review and followup.

To address the comments that found proposed § 111.90 confusing, we have made the following changes in the final rule to simplify the procedures for handling product complaints:

- We replaced the proposed procedure in which a qualified person determines whether a complaint should be investigated by the quality control unit with a procedure in which a qualified person investigates any product complaint that involves a possible failure of a dietary supplement to meet any requirements of part 111.
- We require an oversight function by quality control personnel for the review and evaluation of product complaints, but do not require that quality control personnel do any investigations. This is consistent with other changes that we are making in response to comments that requested that the quality control unit focus on reviewing tasks performed by others rather than on performing the tasks itself.
- We refer to ''any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of this part [part 111], including those specifications and other requirements that, if not met, may result in a risk of illness or injury'' rather than to ''a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event.'' This is consistent with changes that we are making to the definition of the term ''product complaint'' in final § 111.3 (see section VI of this document).
- We continue to require that the review and investigation of the product complaint extend to all relevant batches and records but simplify the language of the requirement by removing the details, i.e., that the investigation must include the batch records associated with the dietary supplement involved in the consumer complaint and not specifying that the investigation must extend to other batches of dietary supplement. Rather, we require that the investigation must extend to all relevant batches and records.

The final rule provides firms flexibility on how to use its human resources. Nothing in subpart O would preclude a qualified person among designated quality control personnel to be designated to actually review product complaints and conduct investigations of any product complaint. If an individual is so designated and conducts the investigation, reviews and approves the findings, and conducts followup actions of any investigation performed, final § 111.560(b) would not apply.

(Comment 320) Some comments object to the requirement in proposed § 111.95(c) that consumer complaints are to be investigated only when there may be a relationship between product quality and an adverse event. These comments suggest this provision be extended to any possible relationship between dietary supplements and adverse events, including those that might be independent of whether the product is produced under CGMPs. These comments consider there should be consistent procedures for handling product complaints, regardless of whether the complaints relate to product quality.

(Response) The action requested in these comments is outside the scope of this rule, which specifically addresses CGMP requirements to ensure the quality of the dietary supplement product. However, we encourage firms to investigate all product complaints in a consistent way, regardless of whether the complaints relate to the quality of the dietary supplement.

(Comment 321) Some comments request clarification of statements made or terms used in the preamble to the 2003 CGMP Proposal regarding the handling of product complaints. In the preamble discussion of proposed § 111.95(c), we stated a consumer complaint about adverse effects ''after consuming several dietary supplements'' is worthy of quality control unit investigation. One comment asks about the meaning of ''several'' and whether this example means that a manufacturer is responsible for consumers who take more than the recommended dosage.

(Response) In our discussion of proposed § 111.95(c) we addressed a situation where a consumer had symptoms on more than one occasion rather than a situation where a consumer took more than the recommended dosage. However, firms must investigate any complaint of illness or injury even if a consumer reports that he/she has consumed more than the amount recommended on the product label to determine if the complaint is related to CGMP.

F. Under This Subpart, What Records Must You Make and Keep? (Final § 111.570)

1. Final § 111.570(a)

Final § 111.570(a) requires you to make and keep the records required under subpart O in accordance with subpart P. Final § 111.570(a) derives from proposed § 111.95(f)(2) with changes associated with the reorganization.

We did not receive comments specific to proposed § 111.95(f)(2).

2. Final § 111.570(b)(1)

Final § 111.570(b)(1) requires you to make and keep a record of the written procedures for fulfilling the requirements of subpart O. Final § 111.553 requires written procedures for fulfilling the requirements of subpart O. Those written procedures are considered a record under final § 111.570(b)(1).

3. Final § 111.570(b)(2)

Final § 111.570(b)(2) requires you to make and keep a written record of every product complaint that is related to CGMP. Final § 111.570(b)(2) derives from proposed § 111.95(e) which would require that you ''* * * make and keep a written record of every consumer

complaint that is related to good manufacturing practices. For the purposes of the regulations in this part, a consumer complaint about product quality may or may not include concerns about a possible hazard to health. However, a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient independent of whether the product is produced under good manufacturing practices.''

As a revision for consistency with the definition of ''product complaint'' in final § 111.3, final § 111.570(b)(2) does not include the two full sentences from proposed § 111.95(e), as quoted in the previous paragraph.

4. Final § 111.570(b)(2)(i)

Final § 111.570(b)(2)(i) requires that the person who performs the requirements of subpart O, at the time of performance, document and record the performance. Final § 111.570(b)(2)(i) is similar to proposed § 111.95(f)(1) with changes associated with the reorganization.

5. Final § 111.570(b)(2)(ii)

Final § 111.570(b)(2)(ii) requires that the written record of the product complaint include: (1) The name and description of the dietary supplement; (2) the batch, lot, or control number of the dietary supplement, if available; (3) the date the complaint was received and the name, address, or telephone number of the complainant, if available; (4) the nature of the complaint including, if known, how the product was used; (5) the reply to the complainant, if any; and (6) findings of the investigation and followup action taken when an investigation is performed. Final § 111.570(b)(2) is similar to proposed § 111.95(e)(1) through (e)(6) and includes a change we are making after considering comments to proposed § 111.95(e)(4) (discussed in the following paragraphs) which would have required that the consumer complaint written record include ''The nature of the complaint including how the consumer used the product.'' On our own initiative, we also made a change to include the date the complaint was received.

(Comment 322) One comment notes proposed § 111.95(e)(4) would require the written record of consumer complaints to include ''how the consumer used the product.'' The comment notes this information may not always be available and suggests the words ''where known'' should be added.

(Response) We agree that there can be circumstances where the firm that receives the product complaint may not know how the product was used. For example, a consumer may make a complaint by leaving a telephone message before or after business hours and neither describe how the product was used, nor leave contact information so that the firm could followup with the consumer. To address this comment, we provide in the final rule that the written record of the product complaint include ''the nature of the complaint including, if known, how the product was used.''

(Comment 323) Some comments request clarification of statements made or terms used in the preamble to the 2003 CGMP Proposal regarding the handling of product complaints. In our discussion of proposed § 111.95(e) we recommended that consumer complaints and investigations be reported to us when consumption of a dietary supplement may be related to ''a serious adverse event.'' Some comments note that ''serious'' is not defined.

(Response) The term ''serious adverse event'' is widely used in the industries we regulate. Our current forms for reporting ''serious adverse events'' via the MedWatch program do not define the term, but instead list outcomes that were attributed to an adverse event. These outcomes include death, life-threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention to prevent permanent impairment/damage, and ''other.'' As discussed in this section, however, there is a new statutory requirement for mandatory reporting to FDA of serious adverse events enacted in the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462). The new law does define ''serious adverse events'' as those events that result in death, a life-threatening situation, an inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect or one that requires medical or surgical intervention to prevent such serious outcomes (based on reasonable medical judgment). The law also has specific provisions for how these serious adverse events are to be submitted to FDA and record retention for records relating to these and other adverse event reports. We anticipate issuing guidance on implementation of the new statutory provisions. We encourage firms who are unsure as to whether the nature of a reported adverse event should be reported to FDA to contact us for assistance.

XXI. Comments on Records and Recordkeeping (Final Subpart P)

A. Organization of Final Subpart P

In the 2003 CGMP Proposal, the requirements for records and recordkeeping were set forth in proposed § 111.125. As shown in table 17 of this document, we are reorganizing the requirements for records and recordkeeping into a distinct subpart (final Subpart P—Records and Recordkeeping). Table 17 lists the sections in final subpart P and identifies the proposed provisions that form the basis for the final rule.

TABLE 17.—DERIVATION OF SECTIONS IN FINAL SUBPART P

Final Rule	2003 CGMP Proposal
§ 111.605 What requirements apply to the records you make and keep?	§ 111.125(a) and (b)
§ 111.610 What records must be made available to FDA?	§ 111.125(b) and (c)

B. Highlights of Changes to the Proposed Requirements for Records and Recordkeeping

1. Revisions

The final rule reflects that it applies to persons who manufacture, package, label, or hold a dietary supplement unless subject to an exclusion in § 111.1.

2. Changes After Considering Comments

This final rule requires you to keep written records required by this subpart for either 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records (final § 111.605(a)).

C. General Comments on Proposed § 111.125

(Comment 324) Some comments support the requirements in proposed § 111.125 because documentation helps to ensure CGMPs are consistently followed and retention of records provides an effective trail when subsequent problems need to be identified and corrected.

Another comment asserts the recordkeeping requirements would represent a large burden for companies that manufacture vitamin and mineral supplements with a large number of active ingredients.

(Response) We agree that records are useful in identifying manufacturing problems and tracking the source of failures in CGMPs.

We understand the burden on manufacturers may be heavier for manufacturers who use many dietary ingredients and discuss the burden of the recordkeeping requirements in sections XXVIII and XXIV of this document. However, we do not believe that a manufacturer who elects to put several components into one finished batch of dietary supplement would necessarily have a larger burden than one who, instead, elects to manufacture multiple dietary supplements each containing one component. We believe that the requirements, for example, for ensuring the identity, purity, strength, and composition of each component in a dietary supplement need to be the same for a dietary supplement containing one ingredient or component and one containing multiple ingredients or components. To the extent the comment is suggesting that the recordkeeping requirements for those who manufacture multivitamin/mineral dietary supplements (containing components) are too large and should be less, the comment provided no basis for such a change.

D. What Requirements Apply to the Records That You Make and Keep? (Final § 111.605)

1. Final § 111.605(a)

Final § 111.605(a) requires you to keep written records for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records. Final § 111.605(a) derives from proposed § 111.125(a).

(Comment 325) Several comments suggest that the requirement in proposed § 111.125(a) to keep records for 3 years beyond the date of manufacture should be modified. One comment favors record retention for 3 years beyond the date of manufacture or for the shelf life of the product, whichever is longer. Some comments state the rule should require establishment of an expiration date and that the manufacturer should have the option of retaining records for 1 year beyond the expiration date, when an expiration date has been established by the manufacturer. Some comments point out that under section 306(a) of the Bioterrorism Act, FDA is authorized to issue recordkeeping regulations with a record retention period of ''not longer than two years.'' One comment, therefore, asserts CGMP records should not be kept for more than 2 years.

(Response) We believe a record retention period for records related to CGMP requirements should correlate generally with the length of time that product complaints are likely to arise related to the manufacture of a dietary supplement. Such correlation will increase the likelihood that, if a problem with a dietary supplement is identified that may be associated with a violation of CGMP, the dietary supplement manufacturer, packager, labeler, or holder will have access to the CGMP records associated with that dietary supplement. In addition, we will have access to such records at inspection.

We have modified the final rule to require a record retention period of 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records or 1 year past the shelf life date, if shelf life dating is used.

A significant portion of the dietary supplement industry use shelf life dating. It is likely that if there are product complaints related to a product these will arise during the shelf life of these products. To ensure there is adequate time to examine the records, determine if there are related manufacturing problems, and implement corrective actions, it is necessary to require the retention of records for 1 year past the shelf life date. This will help ensure that establishments have access to such records to perform the necessary CGMP actions.

For those dietary supplements without shelf life or expiration dating, we believe that 2 years from the date of distribution is a reasonable estimate of the time needed to retain records in order to address CGMP problems identified in product complaints.

It is important to note that, as discussed in this section, the term ''shelf life dating,'' includes shelf life dating as well as expiration dating and ''best if used by'' dating.

We disagree with the comment that suggests we require an expiration date on all products. Many products will not have a determinable expiration date due to the state of knowledge about these products. We believe the manufacturer is in the best position to determine if its product requires an expiration date.

(Comment 326) One comment requests clarification of the ''date of manufacture.'' The comment asserts if an expiration date is shown on the label of a product, the date of manufacture should be considered to be the date on which the expiration date is based. The comment gives an example of vitamin C tablets having a 2-year shelf life. The comment explains if the tablets are compressed, tested, and approved for packaging in August 2003, they would generally be assigned an expiration date of August 2005 regardless of the date of packaging. The comment argues if the tablets are held and later packaged in February 2004, records for this batch should only have to be kept for 1 year beyond the expiration date (i.e., August 2006), rather than 3 years beyond the packaging date (i.e., February 2007).

(Response) In the scenario described in the previous paragraph, where an expiration date (shelf life) has been determined, records for this batch must only be kept for 1 year beyond the expiration date (i.e., shelf life date). The packaging date in the scenario has no effect on the amount of time records must be kept. However, in the final rule, we have decided that it is more appropriate to determine the record retention period from the date of distribution rather than the ''date of manufacture.'' The date on which the manufacturer completes the manufacture of a batch of a dietary supplement (the date of manufacture) does not necessarily indicate the availability of the dietary supplement product in the marketplace. It is possible that such product could be held for a period of time before entry into the marketplace and possible consumer consumption. A more accurate time period for entry is calculated by the date of distribution. Final § 111.605(a)(2) requires that manufacturers, packagers, labelers, and holders keep their records for 2 years from the date of distribution of the last batch of dietary supplement associated with those records. For products with a shelf life date, the records associated with those dietary supplements are required to be kept for 1 year past the shelf life date of that particular dietary supplement. Packagers and labelers that return the product to the manufacturer for distribution are not required to keep separate records under this subpart.

2. Final § 111.605(b)

Final § 111.605(b) requires you to keep records as original records, true copies (such as photocopies, microfilm, etc.), or as electronic records. Final § 111.605(b) derives from proposed § 111.125(b).

We did not receive comments specific to proposed § 111.125(b).

3. Final § 111.605(c)

Final § 111.605(c) requires that all electronic records comply with part 11 (21 CFR part 11). Final § 111.605(c) derives from proposed § 111.125(b).

(Comment 327) One comment believes part 11 should only apply to records that do not have paper counterparts.

(Response) This comment is beyond the scope of this CGMP rulemaking.

(Comment 328) One comment suggests the proposed requirement that CGMP electronic records must comply with part 11 should be deleted because the FDA guidelines on part 11 have not yet been finalized.

(Response) Part 11 applies to electronic CGMP records. Therefore, final § 111.605(c) requires that all electronic records, including electronic signatures, must comply with part 11. We have finalized guidance for industry. The guidance entitled ''Part 11, Electronic Records; Electronic Signatures Scope and Application,'' sets out our enforcement policies with respect to certain aspects of part 11 (Ref. 33). The guidance is available at *http://www.fda.gov/cder/guidance/5667fnl.htm*. The guidance applies to any CGMP electronic records and signatures.

E. What Records Must Be Made Available to FDA? (Final § 111.610)

1. Final § 111.610(a)

Final § 111.610(a) requires you to keep records, or copies of such records, required by this final rule, readily available during the retention period for inspection and copying by FDA when requested. Final § 111.610(a) derives from proposed § 111.125(c). We responded in section V of this document to comments that we received on FDA's statutory authority to inspect and copy records. We made one editorial, nonsubstantive change from the language in proposed § 111.125(c). We removed the word ''authorized'' to prevent any confusion regarding whether some authorization other than the statutory authority that provides the legal basis for this final rule is necessary for our access to inspect and copy records.

2. Final § 111.610(b)

Final § 111.610(b) requires that if you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to us. Final § 111.610(b) derives from proposed § 111.125(b).

We did not receive any comments specific to proposed § 111.125(b) and final § 111.610(b).

XXII. Other Comments and Miscellaneous

A. Comments on Guidance Documents To Be Used With the Final Rule

In the 2003 CGMP Proposal, we invited comment on the usefulness of guidance documents, education, training, or other approaches and potential sources of education and training that would assist industry efforts to implement the 2003 CGMP Proposal, if finalized as proposed (68 FR 12157 at 12163).

(Comment 329) A few comments state booklets, videos, seminars, and other training would be useful on topics such as sanitation, recordkeeping, quality assurance methods, microbiological testing, and botany. Another comment states a subset of CGMPs that focuses on plant authenticity, purity, proper handling, and hygiene should be developed for parties who exclusively deal with bulk raw agricultural commodities (with the exception of individual wildcrafters). If such CGMPs are not developed, the comment requests we develop guidance documents on the identification, cultivation, and handling of botanicals. The same comment also notes guidance specifically is needed on the use of microscopy to identify plants.

(Response) We acknowledge these comments and, in the future, we may issue guidance that relates to certain dietary supplement CGMP requirements.

B. Comments on Consideration for Other CGMP Programs

(Comment 330) One comment asserts several existing dietary supplement CGMP programs (e.g., those developed by the NNFA, NSF International, ANSI, and USP) are well designed and represent useful examples for us to follow. The comment notes section 12(d) of the National Technology Transfer and Advancement Act directs Federal agencies to use such voluntary consensus standards whenever possible, as long as the standards are consistent with Federal law and are practical. The comment recommends we include standards from these existing CGMP programs where suitable in the final rule.

(Response) In the development of the 2003 CGMP Proposal and this final rule, we carefully considered the comments that recommended aspects of other CGMP programs. For example, as discussed previously, the 1997 ANPRM for this rule contained the entire text of an outline presented to us by representatives of the dietary supplement industry. Furthermore, where comments recommended aspects of other CGMP programs, we considered those recommendations and, in some cases, incorporated certain recommendations into requirements in this final rule (e.g., the use of a certificate of analysis).

In 2006, ANSI updated its Standard 173 (ANSI Standard 173) regarding dietary supplements (Ref. 35). ANSI Standard 173 contains provisions for dietary supplement CGMP that are based, in part, on the industry submission to FDA in November 1995, which the agency published as part of its 1997 ANPRM. We considered comments to the 1997 ANPRM, many of which commented on the provisions of the industry submission, and the comments to the 2003 CGMP Proposal in the course of developing this CGMP final rule. We have considered the provisions contained in the updated ANSI Standard 173 and many of the specific provisions contained in ANSI Standard 173 are similar to provisions adopted in this final rule. For example, both the ANSI standard and this CGMP final rule have similar requirements on written procedures, personnel qualifications, record retention, and quality control. However, we determined that adopting the entire ANSI Standard 173 would be impracticable. There are key provisions which reflect major differences between the latest ANSI Standard 173 and the CGMP final rule. Many of these differences are in the product testing environment. For example, the ANSI standard contains different product testing frequency and production stage requirements. We have extensively discussed the justification for the particular testing requirements adopted in this CGMP final rule, which we believe are no more burdensome than the ANSI Standard 173 requirements. For example, the ANSI Standard 173 contains testing methods for metal or microbiological contaminants not included in the final rule. We found that providing flexibility for manufacturers to choose their own specific test methods was a more efficient way of reaching the goals of the CGMP final rule than specifying and requiring particular tests. We support, however, the use of the ANSI Standard 173 testing methods by manufacturers, where appropriate, in complying with the requirements of this rule.

(Comment 331) Another comment states CGMPs that reflect common elements and areas of uniqueness should be placed in subcategories of CGMPs as is the case with the current food CGMP model. The comment recommends we follow a similar

approach and establish subcategories of CGMPs for dietary supplements (e.g., for vitamin-mineral and probiotic tablets).

(Response) In the 1997 ANPRM, we asked for comment about whether broad CGMP regulations would be adequate, or whether it would be necessary to address the operations of particular segments of the dietary supplement industry (68 FR 12157 at 12174). Based on the comments received to the 1997 ANPRM, we were persuaded that a broad final rule is preferable to multiple regulations focused on particular segments of the dietary supplement industry, or to general CGMP provisions plus subcategories applicable to segments of the dietary supplement industry. We stated in the 2003 CGMP Proposal that we would consider whether we needed to re-evaluate our decision to establish one set of requirements for all dietary supplements (id.). This comment did not provide any basis to persuade us to re-evaluate the decision we made that a broad CGMP rule was appropriate. Thus, in this final rule, we are establishing one set of requirements for all persons who manufacture, package, label, or hold dietary supplements and not subject to an exclusion under final § 111.1.

C. Comments on Public Involvement

1. Public Involvement

(Comment 332) Several comments express general concerns with our public involvement process. Several comments state additional public meetings and workshops are necessary to permit FDA, industry, and other stakeholders to work together to seek a more workable solution to dietary supplement CGMPs and to resolve differences of opinion. One comment states the differences of opinion identified by the comment process will not be meaningfully resolved without active and forthright communication with stakeholders. According to the comment, we should establish a forum prior to the publication of the final rule to communicate our perception of these differences of opinion. In another comment, a trade association expresses disappointment that our 2003 CGMP Proposal disregards industry efforts to draft CGMPs over the last decade. Another comment contends the proposal was rushed and the comment period was established without publication of a core economic analysis to support it.

(Response) We disagree with these comments. We believe there has been sufficient public involvement given the public meetings that were held and the opportunity for comment during the comment periods provided. We discuss the public involvement in section I of this document. Further, the 2003 CGMP Proposal did contain an economic analysis. We received extensive comments on the economic analysis in the 2003 CGMP Proposal. We have made several changes to the economic analysis of this final rule in response to these comments as discussed in section XXIV of this document. Furthermore, we have made various changes in response to comments to the CGMP requirements in this final rule.

D. Comments on Implementation and Enforcement

(Comment 333) Several comments suggest postponing the effective date of the rule for 24 months to allow a voluntary inspection and compliance program to take effect in the interim. One comment recommends adoption of a voluntary program similar to that of OSHA regulations in Title 29 of the Code of Federal Regulations, where companies would invite FDA inspection without penalty or cost unless a serious violation occurs. In cases of serious violation, companies would have the option to voluntarily correct the problem and inform the public before the effective date of the rule.

(Response) We disagree with these comments regarding the establishment of a voluntary compliance period. The effective date of this final rule is 60 days after the date of its publication in the **Federal Register**. However, as discussed in sections VI and XXIV of this document, we have staggered compliance dates to 12 months, 24 months, and 36 months, respectively, after the final rule's publication date for businesses of over 500 employees, businesses with under 500 employees but 20 or more employees, and businesses with less than 20 employees.

(Comment 334) Several comments indicate they want differential treatment under the final rule based on the seriousness of a violation, others ask for strict enforcement, and others ask how FDA would enforce against those who continually adulterate dietary supplements.

(Response) We consider these comments to be outside the scope of this final rule. In general, we would provide guidance on our enforcement policy through the issuance of guidance documents if we determine that any variance from full enforcement is warranted.

(Comment 335) Another comment expresses concern the 2003 CGMP Proposal works at ''cross purposes'' with recent regulations associated with bioterrorism. The comment recommends these rules be harmonized to reduce costs and increase efficiencies for manufacturers.

(Response) It is not clear what the comment means when it states the 2003 CGMP Proposal works at ''cross purposes'' with the regulations issued under the Bioterrorism Act or that we should ''harmonize'' the regulations issued under the Bioterrorism Act with the final rule establishing dietary supplement CGMP requirements. We have made every effort to consider the regulations issued under the Bioterrorism Act and their relationship to this final rule. There are different purposes to the Bioterrorism Act and these CGMP requirements; however, we have harmonized to the extent possible.

(Comment 336) One comment states the 1-year compliance period for large firms is reasonable as long as we modify the rule to better reflect existing CGMPs already in practice among responsible companies. The comment also notes the 3-year compliance period for small firms may be reasonable, but urges us to enforce compliance of basic food GMP requirements, which some of these firms may not be observing.

(Response) The effective date for this final rule is 60 days after its date of publication in the **Federal Register**, though we are staggering the compliance dates as described in sections VI and XXIV of this document. Dietary supplement products in the marketplace must already be in compliance with all other statutory and regulatory provisions that affect dietary supplements.

E. Removal of References to Part 112

The 2003 CGMP Proposal (68 FR 12157 at 12175) had proposed the heading and table of contents for part 112. Proposed part 112 had the heading ''Restrictions for Substances Used in Dietary Supplements.'' At the time, we said that it was necessary to amend part 112 because at that time the proposed rule for dietary supplements containing ephedrine alkaloids (62 FR 30678, June 4, 1997) had not been finalized and included proposed revisions to part 111. The 2003 CGMP Proposal for dietary supplement CGMPs proposed using part 111 and proposed the relocation of the ''Restrictions for Substances Used in Dietary Supplements'' to part 112. Since the issuance of the 2003 CGMP Proposal, the final rule for dietary supplements containing ephedrine alkaloids has been finalized (69 FR 6788, February 11, 2004) and has been included in 21 CFR part 119. Thus, there is no need to reserve part 112 in this final rule. The references to part

112 have been removed from the final rule.

XXIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are given in the following paragraphs, with estimates of the one-time burden of establishing written procedures and the annual recordkeeping burden. Included in the burden estimates are the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

Description: Section 402(g) of the act gives us explicit authority to issue a rule establishing current good manufacturing practice requirements for dietary supplements. Section 402(g)(1) of the act states that a dietary supplement is adulterated if ''it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.'' Section 402(g)(2) of the act authorizes us to, by regulation, ''prescribe good manufacturing practices for dietary supplements.'' Under section 701(a) of the act (21 U.S.C. 371), FDA may issue regulations necessary for the efficient enforcement of the act. Other relevant legal authority is discussed in section V of this document.

We did not receive any direct comments on the Paperwork Reduction Act analysis of the 2003 CGMP Proposal. Many comments on the estimated costs of the 2003 CGMP Proposal stated that we underestimated the annual number of batches of dietary supplements produced. Due to a contractor's error, we did underestimate the number of batches produced. This final paperwork reduction analysis corrects for this error. The final analysis also has been revised from the analysis of the 2003 CGMP Proposal in order to incorporate the effects of revisions to the proposed regulation, including reorganization.

Records are an indispensable component of CGMP. The records required by this final rule provide the foundation for the planning, control, and improvement processes that constitute a quality control system. Implementation of these processes in a manufacturing operation serves as the backbone to CGMP. The records will show what is to be manufactured; what was, in fact, manufactured; and whether the controls that the manufacturer put in place to control the identity, purity, strength, and composition and limits on contaminants and to prevent adulteration were effective. Further, records will show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. Further, records will show whether and what deviations from control processes occurred, facilitate evaluation and corrective action concerning these deviations (including, where necessary, whether associated batches of product should be recalled from the marketplace), and enable a manufacturer to assure that the corrective action was effective. In addition, by requiring records, we will be able to ensure that you follow CGMPs so that you ensure the quality of your dietary supplements during manufacturing, packaging, labeling, or holding operations. The final rule establishes the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling or holding operations.

The records requirements of this final rule include written procedures and records pertaining to: (1) Personnel; (2) sanitation; (3) calibration of instruments and controls; (4) calibration, inspection, or checks of automated, mechanical, or electronic equipment; (5) maintaining, cleaning, and sanitizing equipment and utensils and other contact surfaces; (6) water used that may become a component of the dietary supplement; (7) production and process controls; (8) quality control; (9) components, packaging, labels and product received for packaging and labeling; (10) master manufacturing and batch production; (11) laboratory operations; (12) manufacturing operations; (13) packaging and labeling operations; (14) holding and distributing operations; (15) returned dietary supplements; and (16) product complaints.

Description of Respondents: Manufacturers, dietary supplement manufacturers, packagers and re-packagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses.

The recordkeeping requirements of the final rule are set forth in each subpart. In table 18 of this document we list the one-time burdens associated with establishing written procedures. In table 19 of this document we list the annual burdens associated with recordkeeping. In each table, where the same records are mentioned in more than one provision of a subpart, we list the burden under the provisions corresponding to the heading, ''Under this subpart, what records must you make and keep?'' For some provisions listed in table 19, we did not estimate the annual frequency of recordkeeping because recordkeeping occasions consist of frequent brief entries of dates, temperatures, monitoring results, or documentation that specific actions were taken. Information might be recorded a few times a day, week, or month. When the records burden involves frequent brief entries, we entered one as the default for the annual frequency of recordkeeping. For example, many of the records listed under final § 111.35 in table 19, such as final § 111.35(b)(2) (documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment), involve many short sporadic entries over the course of the year, varying across equipment and plants in the industry. We did not attempt to estimate the actual number of recordkeeping occasions for these provisions, but instead entered an estimate of the average number of hours per year. We entered the default value of 1 as the annual frequency of recordkeeping for these and similar provisions. For final § 111.35, the entry for annual frequency is 1 as a default representing a large number of brief recordkeeping occasions.

In many rows of tables 18 and 19 of this document, we list a burden under a single provision that covers the written procedures or records described in several provisions. The burden of the master manufacturing record listed in table 18 under final § 111.210 includes the burden for final § 111.205 because the master manufacturing record must include those written procedures. Similarly, the burden of the batch production records listed in table 19 under final § 111.260 includes the burden for records listed under final § 111.255 because the batch production records must include those records.

The annual frequency for batch production records (and other records kept on a batch basis in table 19 of this document) equals the annual number of

batches. The estimated burden for records kept by batch includes both records kept for every batch and records kept for some but not all batches. We use the annual number of batches as the frequency for records that will not necessarily be kept for every batch, such as test results or material review and disposition records, because such records are part of records, if they are necessary, that will be kept for every batch.

We estimate the burden of this collection of information as follows:

TABLE 18.—ESTIMATED ONE-TIME BURDEN TO ESTABLISH WRITTEN PROCEDURES[1]

21 CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Records	Hours per Record	Total Hours
111.14	15,000	1	15,000	3.6	54,000
111.23	15,000	1	15,000	1	15,000
111.35	400	1	400	36	14,400
111.95	250	1	250	68	17,000
111.140	300	1	300	10.7	3,210
111.180	200	1	200	10	2,000
111.210	250	1	250	12	3,000
111.325	150	1	150	45	6,750
111.375	260	1	260	9	2,340
111.430	250	1	250	12.6	3,150
111.475	15,000	1	15,000	2.1	31,500
111.535	200	1	200	6	1,200
111.570	240	1	240	12	2,880
Total					156,430

[1]There are no capital costs or operating costs associated with the collection of information under this final rule.

TABLE 19.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Number of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
111.14	15,000	4	60,000	1	60,000
111.23	15,000	1	15,000	0.2	3,000
111.35	400	1	400	12.5	5,000
111.95	250	1	250	45	11,250
111.140	240	1,163	279,120	1	279,120
111.180	240	1,163	279,120	1	279,120
111.210	240	1	240	2.5	600
111.260	145	1,408	204,160	1	204,160
111.325	120	1	120	15	1,800
111.375	260	1	260	2	520
111.430	50	1	50	12.6	630
111.475	15,000	1	15,000	0.4	6,000
111.535	110	4	440	13.5	5,940
111.570	240	600	144,000	0.5	72,000
Total					929,140

[1]There are no capital costs or operating costs associated with the collection of information under this final rule.

The burden estimates in tables 18 and 19 of this document are based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute (RTI) in the ''Survey of Manufacturing Practices in the Dietary Supplement Industry,'' OMB Control Number 0910–0422, expiration date April 4, 2000 (Refs. E1 and E2).

The estimates in both tables of the number of firms affected by each provision of the rule are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehousers that reported in the survey that they have not established written SOPs or do not maintain records that would be required under the final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by this final rule, including manufacturers, packagers, labelers, holders, distributors, and warehousers. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as final § 111.260, ''What must the batch production record include?'' The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in final § 111.605. Tables 18 and 19 of this document reflect the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that will be required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with final § 111.605, but have included those burdens under specific provisions for keeping records. For example, final § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and final § 111.255(d) requires that batch production records be kept in accordance with final § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under final § 111.260 (what the batch record must include).

The information collection provisions of this final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, we will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XXIV. Analysis of Impacts

A. Introduction

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this final rule will be an economically significant regulation under Executive Order 12866 because it will have an annual effect on the economy of more than $100 million.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this final rule will be a major rule for the purpose of congressional review.

FDA has examined the impacts of this final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA finds that this final rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The current (2005) inflation-adjusted statutory threshold is $122 million. This final rule qualifies as a significant rule under the statute.

1. Summary of the Economic Analysis

We carry out the cost-benefit analyses required for significant rules in the Final Regulatory Impact Analysis, in section XXIV.B of this document. We perform the Final Regulatory Flexibility Analysis of the effects on the final rule on small businesses in section XXIV.C of this document. We estimate that, once it is fully implemented 36 months after the date of publication, the quantifiable annual benefits from the final rule will be about $44 million. The benefits able to be quantified are generated by more consistently produced dietary supplements which will increase product safety, which reduces the number of acute illnesses and product recalls. In addition, the final rule may generate benefits that we lack sufficient data to quantify. These benefits we cannot quantify arise from dietary supplements manufactured under a system to ensure quality, which leads to a reduction in the number of chronic illnesses and conditions.

The final rule will lead to quantifiable costs of $16 million in the first year it takes effect, $120 million in the second year, and $190 million in the third year. After 3 years, the annual costs will be about $164 million. If we annualize the benefits and costs over 20 years at a 3 percent rate of discount, the annualized quantifiable benefits are $40 million and annualized quantifiable costs are $153 million. These annualized benefits include only those that we are able to quantify. The total annualized benefits may be larger than our estimate of $40 million in quantifiable benefits because of the benefits that we are not able to quantify.

We have determined, based on information contained in this regulatory impact analysis as well as information contained elsewhere in the preamble, that the benefits of this final rule justify the costs.

The final rule will have a significant economic effect on small businesses. We estimate that the annual costs will be about $46,000 for an establishment with

fewer than 20 employees and $184,000 for an establishment with 20 to 499 employees.

2. Summary of Comments on the Economic Analysis

We received numerous substantive comments on the economic analysis of the 2003 CGMP Proposal. In general, comments from the dietary supplement industry state that we underestimated the cost of the 2003 CGMP Proposal. Specific comments from the industry target the 2003 CGMP Proposal's testing requirements, which the comments characterize as ''burdensome.'' Many comments address our estimate of the number of batches of dietary supplements firms produce in a year. Many comments express the fear that, as a result of this 2003 CGMP Proposal, the prices consumers pay for dietary supplements would increase dramatically. Nearly all economic comments mention potential adverse effects of the 2003 CGMP Proposal on small businesses, stating that many firms would have to stop manufacturing. A few comments state that, if made final, the 2003 CGMP Proposal would make dietary supplements more expensive than pharmaceuticals. Other comments address the following topics:

- FDA's other assumptions, including the number of tests required for each batch and the number of tests already being performed.
- Development of analytical methods.
- Equipment and capital investment costs.
- Recordkeeping costs.
- FDA's estimation of benefits.

We will summarize comments on individual substantive issues under the appropriate subject headings and respond.

B. Final Regulatory Impact Analysis

1. The Need for the Final Current Good Manufacturing Practice Rule

The final rule is needed because establishments that manufacture, package, label, or hold dietary supplements may not have sufficient market incentives to use controls to ensure that the characteristics of the supplements are what consumers would choose to buy if they had full or adequate information. Dietary supplements have the characteristics of both experience goods and credence goods.[12] In terms of the acute illnesses discussed below, it may be difficult for consumers to identify the attributes of dietary supplements before the actual consumption of the good. Therefore, it may be difficult, in the absence of some regulation of dietary supplement manufacturing practices, for consumers to differentiate between products produced under good manufacturing practices, and those that are not, at the point of purchase in the marketplace. In terms of dietary supplements as credence goods, consumers may never have adequate information on product characteristics even after the consumption of the good, making it difficult for consumers to determine what benefits each product offers. Because problems can be undetectable, establishments may not adopt the necessary practices to ensure product attributes are as they are intended unless required to do so by regulation.

Of course, the characteristics of dietary supplements, as a type of food product, argue for some sort of Government intervention in this market in order to alleviate the specific market failures that lead to the types of problems with dietary supplements that this rule addresses. There are many types of interventions that may be used to address market failure; FDA has examined the options and has determined that specific CGMPs are necessary for dietary supplements. The rest of this regulatory impact analysis, and particularly section III.A of this document, discusses why FDA has concluded that specific CGMPs are necessary for dietary supplements.

(Comment 337) We received several comments on the need for the 2003 CGMP Proposal. Four comments specifically support the proposal, stating, in part, that they are pleased we are addressing the issue of dietary supplement manufacturing. In addition, one comment states that the 2003 CGMP Proposal was a good step toward providing assurance that dietary supplements are as safe as prescription and OTC drugs.

Other comments express concern about the 2003 CGMP Proposal. One comment generally supports it, but expresses concern that the statements we make regarding market incentives to prevent adulteration and misbranding are inaccurate and misleading. The comment points out that the incentive exists for firms to prevent adulterated products from entering the marketplace because of their desire to avoid damage to their reputations. In addition, adulterated products are already illegal to market. Two other comments support the 2003 CGMP Proposal only with modifications, and another comment supports CGMP regulations, provided they reflect the current ''best practices of leading manufacturers.'' Two comments assert that a ''more rigorous'' enforcement program would be more effective than dietary supplement CGMP requirements in preventing adulteration. Two comments state that a regulation would serve no useful purpose because of the ''low level of harm identified in the industry.''

One comment states that the 2003 CGMP Proposal spells out design standards rather than performance standards. According to the comment, the 2003 CGMP Proposal spells out procedures a firm must follow rather than defining a specific outcome, such as a specified level of contamination. This comment maintains that we should set a performance standard and then allow manufacturers flexibility in how that standard is reached. Another comment states that, although certain dietary supplement ingredients may cause concern, this concern did not justify imposing ''overbearing'' and ''broad'' CGMP regulations for an entire industry. Another comment asserts that the CGMPs as presented in the 2003 CGMP Proposal would serve as an anti-competitive tool by allowing dominant manufacturers to increase their dominance and make it more difficult for new firms to enter the industry.

(Response) Those comments that disagreed with our analysis provided no data or evidence to support the comment. Without such data or evidence, we have no basis upon which to revise our analysis and continue to use the analysis. Thus, we have not made any changes based on these comments.

Whether or not these provisions are performance or design standards is a theoretical issue. Instead of specifically choosing either design or performance standards for all provisions of the rule, FDA has chosen to provide flexibility to manufacturers whenever possible. For example, providing for the use of ''safe and sanitary'' water sources gives manufacturers flexibility in deciding the best way to assure that ''safe and sanitary'' water is used in the manufacture of their products. There are many areas of the rule where more than one way is given to comply with a particular provision. This flexibility allows manufacturers to choose the appropriate means to comply with the provision that is the most cost-effective for them.

[12] An experience good is a product or service where product characteristics such as quality or price are difficult to observe in advance, but these characteristics can be ascertained upon consumption. A credence good is a good whose utility impact is difficult or impossible for the consumer to ascertain even after consumption of the good.

We agree with the comments that point out that existing statutes and regulations, concern for brand names, and voluntary industry standards provide some product safety and quality. Nonetheless, continuing problems in the industry provide evidence for the need for this final rule. From 2000 through 2005, there were a total of 75 recall actions in the dietary supplement industry, including class 1, 2, and 3 recalls of vitamins and minerals and herbal and botanical supplements. We will discuss these recalls, which accounted for about 4 percent of the 1,937 FDA food recall actions in 2000 through 2005, later in this document. Most of these recalls occurred because establishments failed to adhere to product manufacturing or labeling specifications.

For a class 1 recall, there is a reasonable probability of serious adverse health consequences or death; for a class 2 recall, exposure to the product may cause temporary or medically reversible adverse health consequences; for a class 3 recall, exposure to the product is not likely to cause adverse health consequences. Full compliance with the provisions of this final rule could have prevented most of the recalls. We note also recall classifications only track acute hazards, not long-term quality problems. Results from ConsumerLab.com and other independent laboratory results provide further evidence of a need for this final rule (Refs. E3 through E6). Statistical sampling methods were not used to collect the data reported in these analyses. Therefore, although this information provides anecdotal evidence of problems, the data may not be representative of overall industry practices. The information serves as additional evidence of the existence of problems.

Although the final rule will increase the monetary cost of entering the dietary supplement industry, the industry will remain highly competitive with more than a thousand competing producers and thousands more potential entrants.

2. Regulatory Options

We considered several regulatory options for dealing with current manufacturing, packaging, labeling, and holding practices that may not ensure the quality of the dietary supplement. The options considered include: (1) No new regulatory action, (2) fewer requirements for vitamins and minerals, (3) more restrictive regulations than the final rule, (4) HACCP without the other elements of the final rule, (5) final product testing only, (6) a final rule for high-risk products or hazards only, and (7) the 2003 CGMP Proposal.[13] As a result of comments on the 2003 CGMP Proposal and our reconsideration of our position on several provisions, this final rule differs from the 2003 CGMP Proposal.

(Comment 338) We received few comments on the option of fewer requirements for vitamins and minerals, and the comments submitted did not support this option. One comment supports one set of CGMPs that would apply to the entire industry rather than fewer requirements for vitamins and minerals than for botanicals. Another comment states that having fewer requirements for vitamins and minerals would not be wise because of the large number of people who take multivitamin or mineral supplements.

One comment supports more restrictive CGMP requirements, including further testing and quality assurance requirements.

We received two comments that support HACCP without other elements of the final rule. One comment echoes an earlier comment made about stressing outcomes and points to the HACCP systems in the juice and seafood industries as a way of ensuring effective quality control design. The comment asserts that the detailed manufacturing controls and testing requirements spelled out in the 2003 CGMP Proposal may actually stifle innovation. Another comment echoes these thoughts, adding that a HACCP approach could work in tandem with a more traditional specification and test approach.

We received one comment that specifically discusses requiring only final product testing, but received numerous comments on final product testing in general. The specific comment did not support reliance on final product testing only, stating it is not the best or most appropriate control. In addition, the comment claims it is not technically feasible in many cases and is economically burdensome, a point repeated in other general comments about final product testing. In addition, numerous comments point out that a firm cannot ''test in quality,'' meaning that ensuring the quality of the dietary supplement will not be achieved through rigorous end-product testing, which emphasizes the wrong stage of production, but by ensuring quality through an effective process control system.

Few comments discuss regulation of only high-risk products. Those that did note that some ingredients would be of public health concern and it would be preferable to test these ingredients only rather than all ingredients.

(Response) The comments on the regulatory options did not provide evidence to directly support or oppose those options but instead addressed particular issues such as testing or coverage.

We took the comments on specific issues into account in the analysis of this final rule. We discuss them below in the relevant parts of the analysis.

One comment supporting HACCP stated that the detailed manufacturing and testing requirements of the 2003 CGMP Proposal would, compared with HACCP, stifle innovation. Although regulations that impose costs can divert resources away from innovation, the costs of this final rule represent less than 1 percent of industry revenues (see table 35 of this document). Because research and development expenditures account for a small fraction of total expenditures, any reduced expenditures on research and development associated with this final rule will be a small fraction of 1 percent of revenues. Thus, it seems unlikely that this rule would have the effect of stifling innovation. As we explained in the economic analysis of the 2003 CGMP Proposal, the HACCP option would not specify detailed manufacturing requirements but would also fail to ensure product quality (68 FR 12157 at 12222). In section X.I of this document, we discuss why HACCP is not appropriate for dietary supplements. The comment supporting HACCP failed to provide any data or any evidence to support its conclusion. Without such data or evidence, we have no basis upon which to revise our analysis and continue to use the analysis.

3. Coverage of the Final Rule

The final rule applies to establishments that manufacture, package, label, or hold dietary supplements. Tables 20 and 21 of this document list the estimated number of covered manufacturers, packagers, labelers, holders, and other establishments subject to the final rule. Table 20 shows the number of establishments categorized as manufacturers, repackagers or relabelers, holders whose primary business is dietary supplements, and other (although not including other

[13] Options 1 through 6 were discussed in detail in the 2003 CGMP Proposal (68 FR 12157 at 12221 through 12223; March 13, 2003) and analyses of costs were provided when possible. The principles of the options discussion have not changed and are still relevant for purposes of the requirements of the final rule. The 2003 CGMP proposal also included an Analysis of Impacts which contained some errors from a contractor's report. We have corrected the analysis and have recalculated the costs of the 2003 CGMP Proposal. These corrections and recalculations are discussed in section XXIV.B.9 of this document.

holders and distributors). Table 21 shows our estimate of the number of general warehouses, wholesalers, and others that hold dietary supplements, but are not otherwise involved in the industry.

TABLE 20.—COVERED ESTABLISHMENTS BY TYPE OF OPERATION FROM THE DIETARY SUPPLEMENT ENHANCED ESTABLISHMENT DATABASE (DS–EED)

Establishment Type	No. of Establishments	Percent of Establishments
Manufacturer	1,228	84.1
Repackager; relabeler	26	1.8
Holder	114	7.8
Establishments not already classified	92	6.3
Total	1,460	100.0

TABLE 21.—COVERED ESTABLISHMENTS THAT HOLD DIETARY SUPPLEMENTS

Type of Holders	NAICS Code	No. of Establishments
General grocery wholesalers or drug wholesalers	424410	4,036
General warehouse	493110	4,415
Drug wholesalers	42420	7,418
Total		15,869

We consulted several sources to estimate the number of establishments reported in this document. The number, 1,460, is the estimated number of establishments in the DS-EED that manufacture, package, label, or hold dietary supplement products in the United States. In the analysis of the 2003 CGMP Proposal, we included an additional 106 U.S. establishments that supplied dietary ingredients. Because those establishments are not covered in this final rule, we exclude them from the total. RTI developed the DS-EED using FDA's Official Establishment Inventory and supplemented that source with information from trade organizations, trade shows, and electronic databases (Refs. E1 and E2).

To estimate the total number of establishments that could hold dietary supplements but do not consider dietary supplements as their primary business, we first looked for a count of establishments that had North American Industrial Classification System (NAICS) codes for wholesalers of groceries or drugs. Next we looked for a count of firms that met the description of warehouses for groceries or drugs. We did not find a category devoted exclusively to food and drug warehousing, so we concluded that general warehousing most closely corresponded to the set of establishments that would hold dietary supplements. The results are shown in table 21 of this document. This total differs from the total reported in the analysis of the 2003 CGMP Proposal because the new classification system allows us to identify more establishments that would not hold dietary supplements and therefore exclude them from the total.

Foreign firms that export dietary supplements to the United States must satisfy the requirements of this final rule. We do not have data on the number of foreign firms that export dietary supplements to the United States. The small number of foreign products in the FDA dietary supplement sales database suggests that relatively few foreign firms export dietary supplements to the United States (Ref. E7). The foreign firms that will be most affected by the final rule are suppliers of dietary ingredients. Although suppliers of dietary ingredients are not directly covered by the final rule, the need of manufacturers to meet the ingredient specifications required by the final rule will indirectly affect foreign suppliers (as well as domestic suppliers).

No comments were received on the economic analysis of the coverage of the 2003 CGMP Proposal.

4. Baseline Practices

a. *Consumption.* Baseline risks depend on baseline consumption of dietary supplements. Total sales in 2004 were about $20 billion (Ref. E8). Vitamins and minerals accounted for about 42 percent of sales. Sales of herbal supplements, which have not grown in recent years, were half as large as sales of vitamin and minerals, accounting for about 21 percent of the total. Amino acids, proteins, animal extracts, tea-like supplements, and other supplements not otherwise classified accounted for the remainder of sales.

There were no comments on the consumption baseline.

b. *Manufacturing.* We contracted with RTI to conduct a survey of the dietary supplement industry to learn about both baseline (existing) manufacturing practices and the existing standards used for manufacturing dietary ingredients and dietary supplements (Ref. E2). A sample of 966 dietary supplement establishments from the DS-EED database was selected from an estimated eligible population of 1,566 firms in the industry (the total number of dietary supplement establishments included 106 ingredient manufacturers, who are now excluded from the requirements of the final rule). The eligibility criteria and the response rate for the survey are fully explained in the final report on the survey (Ref. E2). We further classified the target firms by product and by size. The product categories were: (1) Vitamins and minerals; (2) amino acids and proteins; (3) herbals and botanicals, including

extracts; and (4) supplements not already classified.

The Small Business Administration classifies companies as ''small'' based on the size of the entire company, including both parent and subsidiaries. If firms that manufacture dietary supplements have fewer than 500 employees, they are classified as small. In addition, for purposes of this analysis, we classify firms with fewer than 20 employees as very small.

We received 238 completed surveys. Table 22 of this document shows the number of completed surveys by product and by size of establishment.

TABLE 22.—NUMBER OF COMPLETED SURVEYS BY SAMPLING STRATA

	Size				
	Very Small (fewer than 20 employees)	Small (20 to 499 employees)	Large (500 or more employees)	Unknown	Total
Vitamins and minerals	19	39	13	1	72
Amino acids, proteins	8	7	0	5	20
Herbals and botanicals, including extracts	58	25	0	30	113
Supplements not already classified	14	13	2	4	33
Total	99	84	15	40	238

(Comment 339) We received two comments on manufacturers' baseline practices. One comment expresses concern that, as the information is over 3 years old, it may no longer represent current industry practices. The second comment questions the way we calculated the number of dietary supplement establishments that do not follow any CGMP models. In the 2003 CGMP Proposal, we state that survey data reflect that 36 percent of surveyed establishments do not follow any CGMP models. The comment points out that 26.5 percent of firms responded ''no'' to the question, ''Does this plant follow a published GMP model for the dietary supplement products produced at this plant?'' Furthermore, of the 63 that answered ''no,'' ''at least'' 29 of the firms provided responses indicating the reason they do not follow a published GMP is that they did not manufacture dietary supplement products.

(Response) Although the survey responses are now over 6 years old, they represent the best information we have on the industry and its practices. We have, however, adjusted our estimated costs to reflect the correction of the results from the original survey.

5. Baseline Risk

The current number of illnesses caused by poor dietary supplement manufacturing practices requires data linking illnesses to poor practices. Because these data do not exist, we looked for other information to provide indirect evidence on the problem. We looked at many sources for information, including medical and other literature on adverse events, information from poison control centers, reports to the agency, newspaper and magazine articles, and surveys of users. The literature review was conducted using Medline, Healthstar, Aidsline, Cancerlit, and OldMedline (Ref. E9). We found evidence of many adverse events associated with dietary supplements. For example, in 2003, the American Association of Poison Control Centers received 24,412 reports on events associated with herbal dietary supplements and 57,801 reports on events associated with vitamin and mineral supplements, with 8,653 of the herbal and 5,669 or the vitamin and mineral reports treated in health care facilities (Ref. E10). In addition, we have received many voluntary reports of illnesses caused by dietary supplements (Ref. E11).[14]

The vast majority of these events and those described in other sources we consulted, however, are reported as associated with the ingredients used in the products themselves, not with contamination or other results of poor manufacturing processes. Most of the reports from poison control centers on vitamins and minerals, for example, involved inappropriate ingestion by children (Ref. E10). We have no direct evidence on how many illnesses can be attributed to manufacturing processes. The anecdotal evidence described elsewhere in the preamble suggests that many illnesses could have been caused by poor manufacturing processes, but there are only a few examples of evidence that explicitly link illnesses to manufacturing processes. Examples of illness that were linked directly to poor manufacturing practices include vitamin D toxicity from excessive vitamin D in multivitamins and cardiac glycoside poisoning from botanical dietary supplements contaminated with *Digitalis lanata* (Ref. E12).

With no direct evidence on the number of illnesses caused by poor manufacturing practices, we had to use an indirect approach. We based the approach on our recall records. Class 1 and class 2 recalls all involve defective products that could have caused illness if ingested. Although the recall data cannot be linked directly to illness data, we have found anecdotes, surveys, and some medical literature on illnesses that could be caused by avoidable dietary supplement manufacturing mistakes. We have recall data that show that manufacturing mistakes exist, so we can construct a plausible link between manufacturing mistakes and potential illnesses or injuries. The number of illnesses associated with a manufacturing problem leading to a recall is both variable and uncertain, and could be anything from zero to quite large. Based on data from FDA food and dietary supplement recalls, we concluded that one reported illness per recall is a plausible average, so we assumed that a recall could be a proxy for a single reported illness associated with a defective product.

[14]Mandatory reporting to FDA of serious adverse events is now required as a result of the enactment of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), signed into law on December 22, 2006. The new law requires manufacturers, packers, or distributors of such products to submit reports to FDA about serious adverse events involving such products based on specific information that they receive from the public.

Because there are no active surveillance systems for identifying adverse health events related to dietary supplements, we assume that the total number of illnesses caused by poor manufacturing practices is substantially greater than the number reported.[15] Based on data for drug and vaccine reporting rates in other studies, one study concluded that for dietary supplements, reported illnesses represent approximately 1 percent of total illnesses (Ref. E13). We use the associated multiplier, 100, in our baseline estimate and assume that reporting adverse health events due to poorly manufactured dietary supplements occurs at the same rate as reporting adverse health events caused for other reasons by dietary supplements. Other reporting rates and associated multipliers are, however, plausible. For some hazards that lead to severe events only, we have used a multiplier of 10; the Centers for Disease Control and Prevention have used a multiplier of 38 for *Salmonella* infections and similar food-related illnesses. We show the sensitivity of benefits to the choice of multiplier below.

From 1990 through 1999, we received reports on an annual average of 11.8 class 1 and class 2 recalls of dietary supplements related to manufacturing problems. If we assume that each recall is a proxy for a reported illness, then the total number of illnesses per year is approximately 1,180. We recognize that our procedure generated uncertain estimates of the number of illnesses. With a multiplier of 10, the estimated number of illnesses per year is 118; with a multiplier of 40, the total number of illnesses per year is 472.

We estimate that the monetary value of the health losses for the hazards listed in table 23 of this document as a weighted average of the values attached to the different health outcomes associated with each hazard. We estimate the health losses or fatal cases as the monetary value of a statistical life, defined as the willingness to pay for a small change in the probability of death. We estimate the health losses for non-fatal illnesses as the sum of: (1) The imputed value of lost productivity, (2) the imputed value of pain and suffering, and (3) actual expenditures on medical treatment. We measured lost productivity (defined to include household and market productivity) indirectly with measures of functional state, which includes measures of physical function. We estimated the losses caused by pain and suffering with a symptom-problem index. We combine the functional losses with the pain and suffering into a single index of lost quality-adjusted life years (measured by the Quality of Well-Being Index). We then convert the quality-adjusted life years to dollars by multiplying the index numbers by the dollar value of a quality-adjusted life year. We used direct measures of medical costs, such as payments to physicians and hospitals. We obtained data on the cost of a hospital day and other medical costs from the Health Care Cost and Utilization Project's Nationwide Inpatient Sample, administered by the HHS Agency for Healthcare Research and Quality (Ref. E14).

Table 23 of this document contains summaries of our measures of the health costs potentially caused by known instances of hazards associated with poor dietary supplement manufacturing processes for the decade 1990 through 1999. We estimated the health loss per day for the different levels of illness severity by summing the lost productivity (as measured by functional state) and the loss from pain and suffering (as measured by the symptom-problem index). These losses per day can be interpreted as the difference between a day of normal health and a day of suffering from the health conditions caused by these defective products. The numerical scale is a relative baseline that rests on the notion of a quality-adjusted life day (QALD). The QALD for a day of normal health equals 1; the QALD for death equals 0. The loss of QALDs per illness equals the daily loss multiplied by the number of days the illness lasts. We converted QALDs to dollars by multiplying the index numbers by the dollar value of a QALD. We computed the monetary value of a QALD using three values derived from three different values for a quality-adjusted life year: $100,000, $300,000, and $500,000. These yield values per day of $274, $822, and $1,370. Our base measures use $822; we show the effects of using other values in the sensitivity analysis.

TABLE 23.—SUMMARY OF HEALTH EFFECTS BASED ON POTENTIAL ILLNESS ASSOCIATED WITH RECALLS BETWEEN 1990 AND 1999

	Recall Class	Number of Recalls	Expected Value of Illness	Expected Value of Illness Times Number of Recalls
Chemical				
Copper salts	2	1	$489	$489
Digitalis	1	33	$37,442	$1,235,599
Ephedra	1	1	$177,237	$177,237
Hypervitaminosis A	1	2	$1,264	$2,528
Hypervitaminosis D	2	1	$1,366	$1,366
Lead poisoning (class 1)	1	1	$15,591	$15,591
Lead poisoning (class 2)	2	40	$10,436	$417,451
Niacin	2	2	$5,802	$11,603
Pyridoxine (Vitamin B6)	2	1	$12,085	$12,085

[15] Mandatory reporting to FDA of serious adverse events is now required as a result of the enactment of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), signed into law on December 22, 2006.

TABLE 23.—SUMMARY OF HEALTH EFFECTS BASED ON POTENTIAL ILLNESS ASSOCIATED WITH RECALLS BETWEEN 1990 AND 1999—Continued

	Recall Class	Number of Recalls	Expected Value of Illness	Expected Value of Illness Times Number of Recalls
Selenium poisoning (class 1)	1	1	$755,338	$755,338
Selenium poisoning (class 2)	2	6	$1,288	$7,731
Stannous fluoride	1	1	$1,266	$1,266
Superpotent zinc	2	1	$389	$389
Biological				
Botulism (class 1)	1	1	$494,683	$494,683
Botulism (class 2)	2	1	$2,044	$2,044
Klebsiella Pneumonia	1	1	$774,178	$774,178
Salmonella (class 1)	1	4	$15,298	$61,191
Salmonella (class 2)	2	4	$778	$3,110
Allergenic				
Lactose intolerance	2	1	$396	$396
Undeclared sulfites	1	1	$723	$723
Yellow #5 sensitivity	2	5	$723	$3,616
Yellow #6, red #40, blue #2	2	1	$1,595	$1,595
Physical				
Glass fragments	2	1	$4,241	$4,241
Other				
L-tryptophan (Eosinophilia-Myalgia Syndrome (EMS))	1	7	$1,135	$7,946
Total		118		$3,992,397

The hazards that occurred between 1990 and 1999 are not necessarily the same hazards that would occur today. For example, botulism is rare and may no longer be a hazard associated with dietary supplements, but recalls involving botulism represent generic examples of adulteration that could occur with other substances in the absence of good manufacturing practices. Also, we base our cost estimates on information from 1999, so it is appropriate to estimate benefits from the same time.

(Comment 340) We received a comment that took issue with the way the recalls are counted. The comment asserts it is more appropriate to count each recall action as a separate recall, regardless of the number of different products affected.

The same comment criticizes the inclusion of the outbreak of Eosinophilia-Myalgia Syndrome (EMS) in the table of what is characterized as ''ordinary'' recalls, since this case is analyzed separately as an example of a ''rare catastrophic event.'' The comment states that the outbreak of *Digitalis* should also have not been included in the recall list because it also was a rare event. The comment asserts that FDA announcements and media attention should have led to full reporting of any adverse events.

Other comments generally refer to risk associated with dietary supplements. One comment states that botanical supplements pose minimal risk if dispensed directly to a patient rather than used in an unsupervised setting, and that toxicology and adverse event reports indicate that end-of-process adulteration in herbal clinics is rare. By contrast, another comment states that adverse events related to dietary supplement use led to hospital admissions at one location and that reports of misbranded and adulterated dietary supplements are common.

(Response) We are not changing the way we count recalls. Each different recall will continue to be counted as a separate recall. How recalls are counted, however, does not affect the analysis. The method used in this analysis corresponds to an average of about one reported illness per recall action. A particular event can lead to many recall actions. If we changed the way we counted recalls so as to reduce the number of baseline recalls to correspond to events, the average reported illnesses per recall would rise in proportion. The estimated benefits would not change.

We are no longer including the outbreak of EMS in our analysis of benefits. The product recalls associated with EMS occurred several years after the outbreak that we are now excluding. The continued benefit associated with preventing EMS is associated with

incorporating quality controls aimed at such hazards.

6. Benefits

The benefits of this final rule come from ensuring the quality of dietary supplements. Dietary supplements should contain the listed ingredients in the listed amounts in product forms that disintegrate and dissolve. Dietary supplements should not contain any contaminants that would adulterate the product under section 402(a)(1), (a)(2), (a)(3), or (a)(4) of the act.

Estimating the benefits of preventing adulteration and contamination is straightforward, at least in theory. These benefits are the value of reducing the risk of the acute illnesses and longer-term complications associated with physical, chemical, and microbiological contamination (see table 23 of this document). The direct value of preventing recalls is another source of benefits from preventing adulteration and contamination. We estimate the benefits of preventing adulteration and contamination by first estimating (based on recall data) the number and kinds of illnesses prevented, and then placing a value on preventing those illnesses. We include the recall costs avoided by industry as additional benefits of preventing adulteration and contamination.

Estimating the value of ensuring the quality of the dietary supplements and that they are manufactured according to their specifications is difficult in practice because we lack the necessary data on what is missing and how what is missing affects public health. Some dietary supplements have authorized health claim labeling that allows them to state their products may reduce the risk of chronic illnesses or conditions. Ensuring that those supplements are manufactured consistently according to the appropriate specifications will increase their effectiveness in reducing the risk of chronic illnesses. In this analysis, we describe those benefits but are not able to quantify them.

The benefits from the final rule, then, will be:

- Reduced health costs associated with a reduced number of acute illnesses (quantified),
- Fewer product recalls (quantified), and
- Reduced health costs associated with a reduced number of chronic illnesses and conditions (not quantified).

This final rule could also enhance the benefits of the ''Dietary Supplement and Non-Prescription Drug Consumer Protection Act'' (Public Law 109–462), which requires mandatory reporting to FDA of serious adverse events. This final rule includes requirements that will provide the information needed to quickly and accurately conduct a sufficient traceback in the case of an adverse event. This enhanced ability to track information related to serious adverse events will increase both the accuracy and the speed of the response to such events, which may in many cases reduce the number of illnesses or deaths associated with unsafe dietary supplements.

(Comment 341) We received many comments on the estimated benefits. Although we did receive comments that stated the rule would benefit consumers by enhancing public confidence in dietary supplements, many comments state that the estimated benefits in the 2003 CGMP Proposal were overstated. In addition, one comment states that our estimates of benefits are double counted, because the outbreak of EMS was included in the measure of benefits from preventing a large catastrophic event as well as total benefits of reduction of illnesses measured by recalls. Furthermore, comments critical of the benefits state the search cost model used in the analysis is not applicable or the benefits of reduced search costs do not exist, we lack evidence with which to base the estimate of reduced health care costs from elimination of rare catastrophic events, and recalls will not fall to zero as a result of implementing CGMPs.

(Response) We agree with the comment that benefits were overstated because of the inclusion of the outbreak of EMS. We no longer include the value of preventing that or similar outbreaks in our estimate of benefits. Although we do not agree with the comments on the applicability of the search model as a measure of benefits, the empirical difficulties associated with quantifying those benefits have led us to replace the search model with a qualitative description.

We now explain each of the three sources of benefits: Reduced acute illnesses, fewer recalls, and reduced chronic illnesses and conditions.

a. *Reduced health costs associated with a reduced number of acute illnesses*. The final rule will help ensure the quality of dietary supplements, which will lead to improved safety of dietary supplements, reducing the probability of acute illness or deaths caused by manufacturing problems. We estimated the reduction of acute illnesses by using our recall records as evidence of possible illnesses; class 1 and class 2 recalls of dietary supplements all involved adulterated products that could have caused illness if ingested. In the 2003 CGMP Proposal, we estimated the reduction of illnesses from preventing catastrophic events by using the public health effects of the outbreak of EMS that resulted from consumption of contaminated L-tryptophan. We agree with comments questioning the applicability of this outbreak to CGMP, so we are no longer including the value of preventing this outbreak as a benefit of this rule.

We estimated the annual expected health benefits for acute illnesses prevented by taking the values of preventing particular illnesses and weighing them by their likely incidence as indicated by recall data. The acute illnesses prevented that we use to estimate benefits are not actual illnesses, but statistical illnesses (defined as the probability of illness multiplied by the population at risk) prevented by the reduction in risk associated with this final rule. These recalls indicate recurring failures to ensure the quality of dietary supplements. Although each class 1 and 2 recall is estimated to have resulted in some illnesses (which may have triggered the recall), there may also be other manufacturing problems that did not lead to recalls but that did lead to illness. Both situations are part of the baseline number of illnesses and deaths estimated.

We computed the expected health benefits from preventing a single illness (of any type) associated with a recall as a weighted average of all potential illnesses. We then calculated the average health benefits of preventing a single illness associated with a non-fatal class 1 or a class 2 recall as:

Health costs prevented = (QALY x value per QALY) + medical costs

We define QALY as the average quality-adjusted life year per illness; as explained earlier, we computed the average by weighting the quality adjusted life years lost for the probability of each health outcome by the expected frequency of that outcome.

To estimate the number of acute illnesses prevented, we started with the average number of recalls per year for the decade 1990 through 1999. The yearly averages for the decade were six class 1 recalls and seven class 2 recalls. As discussed previously, we then assumed that these recalls represented about 1 percent of all acute illnesses caused by the manufacturing problems leading to the recalls. With that assumption, we estimated that the recalls represented about 530 acute illnesses from class 1 recalls and 650

acute illnesses from class 2 recalls.[16] The illnesses used to estimate the benefits of the final rule represent a sample of acute illnesses that could occur without this final rule. We assume that the benefits computed for the average year from the decade 1990 through 1999 represent the annual average benefits we should expect in the future. We do not assume that the acute illnesses prevented in the future will be identical to those that occurred during 1990 through 1999.

TABLE 24.—HEALTH BENEFITS ESTIMATED USING RECALL DATA FROM 1990 THROUGH 1999

Estimated annual number of acute illnesses prevented (530 class 1 and 650 class 2 recalls)	1,180
Dollar estimate of average health benefit for preventing an acute illness associated with a class 1 or class 2 recall	$33,800
Estimated dollar estimate of annual health benefits	$40 million

The estimated benefits are indeed sensitive to the choice of years. For 2000 through 2005, there were 75 recalls: 29 class 1, 25 class 2, and 21 class 3. The annual averages for 2000 through 2005 are therefore 4.8 class 1, 4.2 class 2, and 3.5 class 3 recalls. We estimate that about 80 percent of the class 1 and class 2 recalls were related to manufacturing problems (for 1990 through 1999 over 95 percent of class 1 and class 2 recalls stemmed from manufacturing problems). With an average of 9 class 1 and class 2 recalls per year, our baseline estimate of total associated illnesses using 2000 through 2005 data is 900 (9 x 100). If this final rule prevents 80 percent of these events, then 720 illnesses will be prevented. We do not use this estimate to calculate baseline benefits for this final rule because we do not have a comparably recent estimate of costs. If the reduced number of recalls reflects increased controls in the industry, then the benefits and costs of this final rule will be lower than what we have estimated.

(Comment 342) We received comments critical of the estimates of reduced illness due to recalls. One comment points out that drugs, despite having stringent CGMP requirements, have a higher rate of recalls than dietary supplements, thus providing evidence that such requirements do not necessarily reduce recalls. Expanding on this thought, other comments state that we seem to assume that new CGMP requirements will reduce human error to zero and no more recalls will occur, which is said to be unrealistic.

Other comments express concern about the 100-fold multiplier used to estimate the costs related to recall-associated illnesses. The comment states that we, besides referencing Walker (2000) (Ref. E13 of this document (Ref. E16 in the 2003 CGMP Proposal)), provided no other information to substantiate the use of the 100-fold multiplier and therefore are being arbitrary. Any other number could be as accurate. In addition, other comments state that it is difficult to believe that the multiplier would be applicable to recalls associated with Klebsiella pneumonia and selenium poisoning, and L-tryptophan, because the severity of the illnesses would certainly have been associated with the highly publicized recalls; that is, they would not have gone unreported.

Some comments present recalculated benefits. One comment estimates benefits from fewer illnesses as a result of the 2003 CGMP Proposal to be $10.9 million, rather than our estimate in the analysis of the 2003 CGMP Proposal of $39 million. This new estimate was arrived at by taking into account what was characterized as double-counted benefits which, as mentioned earlier, were characterized as the inclusion of EMS in the measure of benefits from preventing a large catastrophic event as well as total benefits of reduction of illnesses measured by recalls. Another comment re-estimates the benefits as $16 million. This estimate was calculated assuming 100 percent of potential illnesses related to Klebsiella pneumonia were classified as severe (with none classified as deaths), and 50 percent of illnesses associated with the selenium recall were classified as serious and none were classified as deaths. This comment also disagrees with the assumption that 3 percent of the 100 potentially ill from the recall associated with undeclared ephedra would have died. Furthermore, this comment adjusts the benefits to take into account recalls that this comment felt were erroneously included in the calculation of benefits from reduced illnesses.

(Response) We have not seen any new data or other information that would lead us to change the 100-fold multiplier for our basic estimate. We recognize that the multiplier is uncertain; different multipliers lead to different estimated numbers of illnesses and different estimated benefits. With a multiplier of 10, estimated benefits are 10 percent of our baseline; with a multiplier of 40, estimated benefits are 40 percent of our baseline. The estimated benefits of this final rule, thus, move in proportion to the assumed multiplier. We recognize this uncertainty and show how it affects the estimated benefits in the sensitivity analysis. The multiplier implicitly assumes that the more severe illnesses are more likely to be reported; the average reporting rate for all adverse events is assumed to be about 1 percent. The average incorporates higher reporting rates for more severe illnesses, and lower reporting rates for less severe illnesses.

The comments on the severity weights for Klebsiella pneumonia and ephedra did not persuade us to change these estimates. We based the estimates on the outcomes for severe events associated with these hazards. The Klebsiella weights come from the medical literature (Ref. E9); the ephedra weights are based on adverse events involving ephedrine alkaloids.

The comparison of drug recalls to dietary supplement recalls does not provide data that would cause us to change our analysis. The drug industry is far larger than the dietary supplement industry and any such comparison would have to account for that difference as well as other differences. Expenditures on prescription drugs exceeded $200 billion in 2004.

(Comment 343) We received many comments regarding the use of the outbreak of EMS in 1989 as a basis for estimating health benefits from preventing a catastrophic event. The majority of the comments assert that CGMPs would not have prevented the outbreak. One comment expands this assertion by stating our claim that testing requirements would reduce the probability that contaminated ingredients would be released to the public is incorrect, because it was not known what, if any, contaminants caused the outbreak. Secondly, the comment states that our claim that complaint files would allow for fast identification of an adverse health event is also incorrect because the victims of

[16] In the uncertainty analysis in section XXIV.B.11 of this document, we used a probability distribution to represent the uncertainty associated with the number of illnesses. We modeled the number of illnesses prevented for each class as the average number of recalled products plus a negative binomial distribution representing unknown cases. The negative binomial distribution estimates the number of failures (unknown cases) that will occur before some number of successes (known cases) for a given probability of success. In the negative binomial distribution, we assumed that the numbers of recalls represented reported cases and that the probability of reporting equaled 1 percent (Ref. E13). The mean estimated number of illnesses is 100 times the reported number of recalls.

EMS did not know the L-tryptophan was the cause of their illnesses.

Two other comments question the periodicity for a cycle of potential catastrophic events due to dietary supplements. One comment suggests a period of 70 years rather than our 30 years. The other comment does not suggest a period but rather states that, since we have no data to support the cycle of 30 years, and we admit it is difficult to know how likely rare events are, it is possible that the total projected benefit could be zero.

Lastly, other comments state that the benefits from preventing a rare catastrophic event are double-counted. These comments state these benefits are double-counted because they are also included in the estimation of benefits from reduced recalls.

(Response) As stated previously, we are no longer including estimated benefits from preventing a rare catastrophic event in the analysis of benefits. We continue to include the benefits of preventing statistical cases of EMS in the annual health benefits, because several recalls of L-tryptophan, which could be associated with EMS took place during the 1990 through 1999 period.[17]

b. *Fewer products recalled.* Implementation of the final rule will reduce the number of adulterated products distributed to the public, which will reduce the number of products recalled. Process controls and better recordkeeping will increase the ability of establishments to produce dietary supplements according to specifications and to identify problems before distribution. If adulterated products are caught before they are distributed or earlier in the production process, they will not need to be recalled.

To estimate the direct benefits from fewer recalled adulterated dietary supplements, we estimate the number of annual recalls of dietary supplements that would be prevented by adherence to CGMP requirements in the final rule. From 1990 to 1999, FDA received reports on 195 recalls related to manufacturing problems, an average of 19.5 recalls per year (Ref. E9). The average figure reported here includes class 3 recalls. The number of units of dietary supplements for each recalled product varied, so we used a distribution per recall of 1,000 units to 34,000 units (Ref. E9). Product price (updated to 2004) also varies, with most prices falling between $6 per unit and $11 per unit; we used a most likely price of $8.50 per unit. We include an adjustment for the goodwill lost by the establishment as a result of the recall. We multiply the direct cost of the recall by two in order to include the lost goodwill. We also adjust for recalls that would likely not be prevented by the final rule. The result is an estimated savings of $1.8 million in direct costs and $1.8 million in goodwill, for a total savings of about $3.6 million per year.

(Comment 344) We received several comments on our estimates of the reduction in recalls. As noted previously, a comment generally states that drugs, despite having stringent CGMP requirements, have a higher rate of recalls than dietary supplements, thus providing evidence that CGMPs do not necessarily reduce recalls. Again, other comments state that we seem to hold the unrealistic assumption that the final rule will reduce human error to zero and no more recalls will occur. Another comment points out that the assumption that the final rule would cause the discovery of all adulteration is inconsistent with the requirement that firms keep complaint files. If the rule eliminates adulteration, the comment states, then there should be no complaints to report.

(Response) We do not believe that recalls will fall to zero. We assume that the recalls identified as being preventable by this final rule will fall to zero, but that mistakes and other hazards will continue to generate recalls. In the sensitivity analysis, however, we show the effects of a lower level of effectiveness in preventing recalls associated with manufacturing problems.

c. *Reduced health costs associated with a reduced number of chronic illnesses and conditions.* We cannot quantify the value of ensuring that dietary supplements contain everything in the established specifications (and nothing that is not in the specifications) because we lack the necessary data on what is missing and how what is missing affects public health. The public health benefits are derived from the reduced number of chronic illnesses and conditions. These benefits may arise from known nutritional effects or from uncertain nutritional effects.

d. *Benefits from known nutritional effects.* Many of the nutritional benefits of vitamins and minerals are known and well-documented. For example, the Dietary Guidelines for Americans, 2005 states that dietary supplements can be used to help meet the recommended intakes of vitamin B12, folic acid, and vitamin D (Ref. E15). The Institute of Medicine's Dietary Reference Intakes include statements that supplements can be sources of several vitamins and minerals (Ref. E16). We have recognized the use of supplements in authorized health claims for calcium and osteoporosis (§ 101.72) and folic acid and neural tube defects (§ 101.79).

In table 25 of this document, we list some of the health benefits associated with the consumption of various dietary supplements.

TABLE 25. SELECTED HEALTH BENEFITS FROM CERTAIN DIETARY SUPPLEMENTS

Dietary Supplement	User	Benefit
Folic acid	Women of child-bearing age	Reduces the risk of neural tube defects
Calcium	Children and adults	Reduces the risk of osteoporosis
Iron	Adolescent females and women of child-bearing age	Reduces the risk of anemia
Vitamin D	Children and adults; persons with dark skin, or with too little exposure to sunlight	Reduces the risk of osteoporosis
Vitamin B12	Persons over the age of 50	Reduces the risk of anemia

[17] We recognize, however, that the presence of L-trypotophan only indicates a small probability of EMS. The estimates in table 23 of this document assume that L-trypotophan represents a 0.1 percent probability of EMS.

e. *Benefits from uncertain nutritional effects*. We do not know the full range of effects (or lack of effects) of most dietary supplements. Vitamins and minerals with known nutritional effects in supplement form may have other effects that we have yet to discover. Our uncertainty is particularly large with respect to the nutritional effects of herbal and botanical supplements. The evidence is still too mixed and incomplete to determine the effects of most of these substances. If, however, herbal dietary supplements do indeed have significant beneficial effects on the risk of chronic illnesses and conditions, then if the final rule ensures that the supplements consistently meet their specifications, we should add those benefits to those from supplements having known nutritional effects.

The benefits of this final rule that we can identify are those associated with the known effects. The product deficiency might be, for example, that packages contain some percentage less or more of the necessary ingredient (such as calcium) than what is listed on the label. The relationship between the shortage or excess amount of the ingredient and the probability of chronic illness would also have to be taken into account in order to determine the risk associated with the product deficiencies. The increase in the probability of chronic illnesses may be negligible, less than, the same, or more than the shortage or excess in the amount of the ingredient. The increase in the probability of chronic illness would also depend on how long the supplement contained a shortage or excess amount of the ingredient. Suppose, for example, that a calcium supplement contains 10 percent less calcium than it should for 1 year. If the average consumer takes calcium supplements for 20 years, would the 1-year deficiency of 10 percent increase the probability of osteoporosis by more or less than 0.5 percent (10 percent x (1/20))?

If we could determine the change in the number of chronic illnesses prevented by dietary supplements as a result of this final rule, we could estimate benefits by multiplying the additional number of chronic illnesses prevented by the value of preventing those illnesses. The values consumers place on preventing illness differ across illnesses and across consumers, and are related to the reasons they use dietary supplements. We will illustrate the method with two examples: Calcium and osteoporosis and folic acid and neural tube defects.

Calcium and osteoporosis. Many consumers take calcium supplements to reduce the probability of osteoporosis, which afflicts as many as 10 million people over age 50 (about 8 million women and 2 million men). An additional 34 million men and women may be at risk for developing osteoporosis (Ref. E17). If ensuring that calcium supplements contain what they should reduces the risk of osteoporosis, the total osteoporosis health benefits associated with the final rule will be the number of cases prevented multiplied by the health costs per case. We estimated the health costs per case as the sum of the direct medical costs, the value of functional disability, and the value of the pain and suffering associated with the illness. Cases range in severity from mild to severe. A mild case, for example, might lead to a loss of utility (measured as quality-adjusted life years—a year of life adjusted for the individual's health status) of 0.14 per year for 9 years. If we apply a discount rate of 7 percent to the years the condition lasts, the loss of quality-adjusted life years is about 0.9 (6.5 discounted years x 0.14 lost utility per year). In other rulemakings we have used a range of values for a quality-adjusted life year; the range has been from $100,000 to $500,000, with a medium monetary value of $300,000 (68 FR 41434, July 11, 2003). With a value per year of $300,000, the value of preventing a mild case is about $270,000 (0.9 x $300,000).

A severe case, by contrast, can lead to fractures and permanent disability. Also, osteoporosis in women can occur at early ages and last decades. If someone suffers from osteoporosis for 30 years, the discounted quality adjusted life years lost would be 6.9 (12.4 discounted years x 0.56 lost utility per year). We estimate that medical costs for a severe case can be over $17,000. The value of preventing a severe, long-lasting case is therefore about $2.1 million ((6.9 x $300,000) + $17,000).

Folic acid and neural tube defects. Many women of child-bearing age take dietary supplements to help ensure their own health, and the health of their children should they become pregnant. For example, 40 percent of women aged 18 to 45 take supplements containing folic acid, which may reduce the probability that children will be borne with neural tube defects (Ref. E18). Neural tube defects affect the spine (spina bifida) and the brain (anencephaly). About 3,000 pregnancies are affected each year (Ref. E18).

The benefit of ensuring that folic acid supplements contain what they should equals the population at risk multiplied by the reduction in the probability of neural tube defects, multiplied by the value of preventing a neural tube defect. Neural tube defects involve large medical expenses, and either early death or permanent disability. The lifetime medical costs alone are between $400,000 and $500,000 for spina bifida (Ref. E19, with values updated). In recent rulemakings, we have used $5 million as the value of a statistical life, defined as the willingness to pay for reductions in small risks of premature death. Preventing a statistical death from anencephaly would therefore generate benefits of $5 million to $6.5 million. For spina bifida, one estimate is that an average case leads to a loss of more than 15 quality-adjusted life years, for a monetized loss of close to $5 million for a non-fatal case if valued at $300,000 per quality adjusted life year (Ref. E20). The value of preventing a case of spina bifida, then, is the sum of medical costs and the value of a saving the quality-adjusted life years, or about $5 million ($450 million value of quality adjusted life years + $500,000 direct medical costs).

Estimating the total benefits of this final rule requires estimates of the numbers of chronic illnesses and conditions whose incidence can be further reduced by ensuring that dietary supplements contain what they should. Because we have no information on the baseline number of chronic illnesses caused by deficient or excessive ingredients, or on the change in the likelihood of chronic illness that will occur as a result of the provisions of this final rule, we cannot estimate the full benefits of ensuring that dietary supplements contain what they should. Our quantified benefits for this final rule must therefore consist entirely of the benefits from reducing the risks of acute illnesses and reducing the number of product recalls. The total benefits will be larger by an amount we are not able to quantify.

(Comment 345) We received many comments about the estimated benefits as measured by the value of hypothetical search time.

(Response) We are no longer using the search model.

f. *Total benefits*. The total benefits from the final rule are the sum of the value of health benefits from fewer acute illnesses, the value of fewer product recalls, and the value of the health benefits from fewer chronic illnesses. Table 26 of this document shows the total benefits.

(Comment 346) One comment states that our total estimated benefits could be as little as $21 million.

(Response) Our current estimate of total quantified benefits is $44 million

per year, once the final rule takes full effect. In addition, as discussed previously, there are benefits to this rule that have not been quantified. The unqualified benefits estimate is the mean of a range of estimates based on assumptions about reporting rates and the effectiveness of the final rule.

In the analysis of benefits for this rule there are two large uncertainties: Quantified underreporting of acute illnesses and injuries and nonquantified benefits associated with chronic illnesses. Despite the best efforts by public health authorities, there will always be underreporting of illness and injuries. Where fatalities are concerned, unless there are litigation problems or the potential for the spread of infectious disease, there is no incentive to do extensive forensic work to determine whether a fatality is related to the ingestion of a dietary supplement. This leads to reporting most fatalities under the most general International Classification of Diseases codes. We acknowledge the large uncertainties in our estimate because of these factors.

The degree of prevention of chronic illnesses due to preventing super- or subpotent dietary supplements depends on two factors, both of which are highly uncertain. The first factor concerns product benefit: How many dietary supplements have any beneficial effect on chronic illnesses and how strong are those effects? Recent work in this area so far has examined only a few dietary supplements, with mixed results. Of course, ensuring the potency of an ingredient that has adverse effects or has adverse interactions with drugs would subtract from the benefits. The second factor is the incidence and effects of subpotency and superpotency across products and over time: How much of a difference in the product need there be to generate a substantial adverse health effect? Because of these uncertainties, it is virtually impossible to make any sort of quantitative statement about likely effects of a regulation ensuring against superpotency and subpotency.

Because of the uncertainties in estimating the benefits associated with both chronic and acute illnesses associated with manufacturing practices for dietary supplements, the decision to implement regulatory requirements becomes an exercise in weighing quantitative and qualitative benefits to public health against expenditure of scarce resources. By choosing to go forward with this rule, FDA is exercising precaution with respect to uncertain risks.

In the uncertainty and sensitivity analyses in section XXIV.B.11 of this document, we show how uncertainty and different assumptions generate higher or lower quantifiable benefits. Using plausible assumptions about the uncertain variables, we estimate that total quantified benefits (using 1990 through 1999 data) most likely fall within a range of $8 million to $64 million per year.

TABLE 26.—SUMMARY OF ANNUAL BENEFITS

Benefits	Mean
Fewer acute illnesses	$40 million
Fewer product recalls	$4 million
Fewer chronic illnesses	Not quantified
Total quantified benefits	$44 million

7. Costs

The same changes in manufacturing practices that produce benefits also have opportunity costs. Due to the increased expenditures of complying with this final rule, firms may spend fewer resources on potentially costly activities such as worker safety, product development and marketing, or voluntary testing of the efficacy of their products. The final rule will require dietary supplement establishments to adopt some new practices in order to manufacture, package, label, or hold their products in compliance with CGMP requirements. In some cases, establishments will make capital improvements to the physical plant, add or replace equipment or controls, perform additional maintenance, establish written procedures, keep records, carry out tests, monitor production and process controls, or execute a variety of additional tasks that they may not have previously performed. Not all firms will comply; some will go out of business or move their plants to other countries and not sell their product in the United States. We estimated the additional costs of production associated with the final rule and the leading regulatory options using the survey to estimate baseline manufacturing practices (Ref. E2).

a. *Description of the costs.* To estimate costs for the dietary supplement industry, we initially divided the industry into four product categories and three size categories. Because the survey showed that there were only a few establishments in some categories, we consolidated the size and product into three size categories. The size categories were:

- Very small (fewer than 20 employees),
- Small (20 to 499 employees), and
- Large (500 or more employees).

Although this consolidation glosses over the important differences across products, the purpose is to estimate the broad average costs of the rule.

For each size category, we constructed a cost model that included every provision of the final rule. We then attached a cost to each provision that had an additional activity associated with it. Most provisions did not have costs attached to them, because they were either descriptive or the costs were included elsewhere.

The costs will be the marginal, or additional, costs of the activities producers undertake in response to the provisions of the final rule. In the cost model, we expressed the cost as cost per unit, with the unit being the establishment, the number of employees, or the annual number of batches produced or affected.

b. *Summary of general comments on costs.* We received many comments on the costs of the 2003 CGMP Proposal. Many of the comments were general in nature and addressed the belief that our economic analysis underestimated the total costs of the 2003 CGMP Proposal, both first year costs and annual costs. Numerous comments point to the rule's testing requirements as the main cause of the high costs. Comments also state that the analysis underestimates costs of hiring new workers, capital equipment, and holding and distributing costs. In addition, some comments point out that the economic analysis did not include estimates of costs of holding reserve samples and tracking product complaints.

As a result of the 2003 CGMP Proposal, comments assert, product choice would decline, prices of existing products would increase, and many businesses, particularly small businesses, would be forced to shut down. One comment states there could be a decrease in spending on research and development. Some comments state that the burden on business could be alleviated by allowing the use of certificates of analysis for incoming raw materials and using a statistical, or more flexible, testing regime instead of requiring final product testing on all batches.

A comment from a trade association representing ingredient suppliers and manufacturers in the dietary supplement industry accepts our assumptions on the following variables:

- The number of control points,
- The average number of ingredients per product, and
- The average cost per test.

Other comments, however, state that the average number of ingredients is

higher than estimated and that the average cost per test is higher than estimated; one comment from a manufacturer states that its average cost was 2.5 times our estimate. These comments came from self-described small firms.

(Comment 347) One comment states that we failed to consider start-up costs.

(Response) We include start-up costs (also referred to as set-up or one-time costs) throughout this analysis.

(Comment 348) Many comments on the regulatory impact analysis targeted our estimates of firms' batches per year. Nearly all comments about batches state that our batch estimates are too low. For example, an industry trade groups claims our estimate of 309 batches per year for large firms is ''implausibly low.'' The same comment states that the distribution of the number of batches per firm of 309, 554, and 223 for large, small, and very small firms is ''illogical'' because it does not make sense that large firms would have fewer batches per year than small firms.

(Response) Due to a contractor's error, we used an inaccurate estimate of the annual number of batches in the analysis of the 2003 CGMP Proposal. The analysis of the final rule corrects for this error. The corrected mean numbers of batches per firm are 444 for very small, 2,436 for small, and 1,164 for large firms. The corrected estimates of the number of batches continue to show that small firms produce more batches than large firms. Comments from self-described small firms suggest that this distribution of batches is reasonable. These comments state that small firms produce many small batches of product using machinery with smaller capacity than that used by large firms. Very small firms produce the fewest number of batches per firm of the three size categories because of their much lower output.

(Comment 349) One comment states that we used faulty data in the economic analysis.

(Response) In accordance with our information quality guidelines, we have used the best available data in this analysis. As explained in the response to comment 348, the survey results used in the analysis of the 2003 CGMP Proposal included an inaccurate estimate of the number of batches of dietary supplements produced. We use the corrected estimate in the analysis of this final rule.

(Comment 350) Some comments dispute the estimated testing costs. In particular, comments question our assumptions on:

- The number of tests required per batch,
- The number of tests already being performed,
- The costs to perform specific analytical tests, and
- The development of analytical methods.

(Response) The final rule reduces the number of required tests. In the final rule, we account for tests where no analytical methods have been developed. We now require fewer tests, although we anticipate that some testing will take place associated with the creation of certificates of analysis required for component specifications and as verification for process controls. We now assume that the tests will be:

- One identity test for each shipment lot of incoming dietary ingredients (e.g., vitamin C);
- Tests of subsets of shipment lots by supplier firms to create certificates of analysis for identity of other components (e.g., sugar);
- Tests of subsets of shipment lots for other specifications in the certificates of analysis;
- Tests of subsets of batches of dietary supplements for microbial, chemical, or physical contaminants;
- Tests of subsets of batches of dietary supplements for specifications; and
- Tests for meeting requirements that water used to manufacture dietary supplements complies with Federal, State, and local requirements and does not contaminate the dietary supplement.

We are not changing our estimate of the current prevalence of testing, which is based on the survey of manufacturers (Ref. E2). We would only revise this estimate in light of new data of comparable quality to that provided by the survey.

(Comment 351) We did receive two comments favorable to recordkeeping, stating that master and production batch records were good to adopt and that associated costs will be minimal. One of the comments states that the level of detail may be unrealistic for a small firm, but also states that any final regulation could be made more flexible for small manufacturers.

Although there were favorable comments, we received several comments critical of the recordkeeping requirements. These comments make general statements that the economic analysis underestimates the recordkeeping burden and some added that these requirements go beyond the CGMPs for food. In addition, several of the comments include firms' own estimates of costs of complying with the recordkeeping requirement. Comments estimate costs in the range of $11,000 to $64,000.

(Response) The recordkeeping requirements in the final rule differ from the 2003 CGMP Proposal; revised estimates are included in this final regulatory impact analysis and paperwork reduction analysis.

(Comment 352) We received a favorable comment regarding the requirements for physical plant and equipment, saying that, although the costs would be moderate, the result would be higher quality products. Another comment states that, although not unrealistic, the provision would be very costly.

Other comments are more critical. One comment estimates that renovation expenses would amount to approximately $600 million over the entire industry, as opposed to our estimate of $45 million. This comment states that the reason our estimates in the 2003 CGMP Proposal were too low is that we apply a reduction factor which assumes that 18 percent of very small firms, 10 percent of small firms and 1 percent of large firms will have to make capital improvements. It is more appropriate, the comment states, to assume that most facilities will need to renovate about 10 percent of their plant, regardless of firm size. In addition, the requirement that plants have smooth, hard surfaces on all floors, walls, and ceilings is unrealistic and would add quite a bit of cost. The comment asserts no company will have such surfaces throughout the plant and this is not a requirement in either the food or drug CGMP requirements. Other comments echo the belief that capital expenditures would be greater than our estimates and would be excessively burdensome. One comment estimates this cost at approximately $83,000 per facility.

The comment also estimates that a large firm that needs to expand its capacity could expect to incur costs of $240,000, as opposed to the $2,000 that the comment says we estimated for large firms. In addition, it is pointed out that equipment costs could be burdensome to small firms, which likely do not have well-equipped labs. This thought is affirmed by other comments that estimate that new equipment could cost anywhere from $50,000 to $1 million, with annual costs estimated between $15,000 and $100,000. In addition, expansion of laboratory space is estimated at $200 per square foot, as opposed to the agency's estimate of $50 per square foot. Lastly, one comment suggests we work with the Internal Revenue Service to allow for more rapid depreciation of facility costs to help small businesses make facility upgrades.

(Response) In the analysis of the 2003 CGMP Proposal, we estimated the

number of firms needing to make capital expenditures associated with the rule as a distribution, with the parameters of the distribution determined by the size of the facility. We assume that if a firm does make a capital investment in response to the rule, it would affect about 10 percent of the plant. With an estimated cost of $50 per square foot, and the average size of a very small plant of about 25,000 square feet, the cost per very small establishment making a capital investment would be about $125,000. With the average size of a small plant of about 70,000 square feet, the cost per small establishment making a capital investment would be about $350,000. With the average size of a large plant of about 600,000 square feet, the cost per large establishment making a capital investment would be about $3 million (Ref. E2). We assume that most facilities will not need to make capital investments to meet the sanitation requirements of this final rule as, according to the survey results, most establishments already meet the sanitation standards of this final rule. This would not be possible if their facilities were inadequate. We note that the final rule does not require smooth and hard surfaces throughout the plant.

We estimated the capital costs as the costs of minor renovations to help meet sanitation requirements, not as the cost of, for example, expanding the size of a laboratory or some other technically sophisticated change. Although some facilities may choose to expand laboratories, the testing requirements of this final rule should be able to be met by existing laboratory facilities within or outside of the manufacturing facilities.

Working with the Internal Revenue Service on depreciation is beyond the scope of our authority. We will provide advice on financing capital improvements through our small business representatives in the Office of Regulatory Affairs.

(Comment 353) Many comments address costs resulting from what industry describes as the exhaustive testing requirements outlined in the 2003 CGMP Proposal. Comments point out that the requirement to test every ingredient would be very costly for firms large and small, with many firms stating that they risk going out of business. In addition, several comments add that the testing requirements would do little to enhance product quality. Many comments assert that allowing the use of a certificate of analysis would reduce the amount of tests performed on a shipment of incoming raw materials, reducing redundant testing, and also reducing the risk that a firm may go out of business. Other comments state that allowing statistical testing regimes would also cut down on testing costs.

(Response) As we already have discussed in this section, we have reduced the amount of required testing in this final rule. The final rule requires testing the identity of every incoming dietary ingredient. However, the final rule allows for use of certificates of analysis in place of identity tests of other components and other tests of incoming dietary ingredients and other components. The final rule also allows sound statistical testing regimes for finished products. We recognize, however, that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would provide no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100-percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we decided to provide, in an interim final rule published elsewhere in this issue of the **Federal Register**, a procedure that allows for submission to, and review by, FDA of an alternative to the required 100-percent identity testing of components that are dietary ingredients, provided certain conditions are met.

(Comment 354) One comment states that our cost estimates are based on the assumption of only two ingredient tests, an assumption which the comment calls into question. For multivitamins, one comment estimates about 8 separate tests and 16 separate assays, depending on the nutrients present.

(Response) In the analysis of this final rule, we assume one identity test per incoming shipment lot of dietary ingredients based on the revisions made to the final rule compared with the 2003 CGMP Proposal.

(Comment 355) Many comments include individual estimates of testing costs. For example, two comments estimate an average cost of about $100 per test, and other comments estimate averages as high as $360, as opposed to our estimate of about $60 per test. Several other comments claim that the costs of finished product testing alone would be ''at least 100 times'' greater than our estimates; other comments state that testing costs would almost equal the costs of manufacturing. One comment estimates testing costs for firms of all sizes at $245 million, as opposed to our estimate of $24 million, although another contains estimates as high as $13.6 million annually for one firm. Two comments concede that some finished product testing may be necessary.

In addition, some comments state that our estimate of finished and raw material testing is off by a multiple of three to six. One comment states that, for companies that have products which contain a large number of ingredients expensive to test, very large costs will be incurred. This comment also states that our cost estimates do not include in-process testing, which they claim the rule would clearly require. Specifically, our analysis suggests that an average of 2.5 in-process tests per batch are likely to be needed at critical control points. In addition, the comment maintains that our analysis showed that additional testing may be required for an average of 2.5 components of herbal products and 7.5 components of vitamin products, but our estimates do not include costs of the tests. Finally, comments point out that, if the production system is properly controlled, then a ''reduced schedule'' of final product testing is justified and that focusing excessive resources on end-product testing does not constitute GMP. Quality controls should be built into the production and process system from the beginning of the manufacturing process.

A comment also states that our estimates of firms that already test are inaccurate. The comment asserts that our estimates are overstated and they also think we have understated that proportion of finished batches not currently being tested. In addition, the comment claims that ''even large firms that are testing 90 percent of their products are unlikely to be performing the exhaustive level of testing required by the 2003 CGMP Proposal, namely testing every component of every batch of finished product.''

The comments point out that our cost estimates do not include estimates for the cost of developing methods of analysis for ingredients. At a minimum, one comment states this estimate should be $2 million (the cost of 100 methods at a minimum of $20,000 each). Several comments point out that often there are no existing scientifically valid analytical methods to test finished products, especially botanical products. Another comment states that costs of analytical testing are at least three times our estimate, and could be as high as eight times our estimate. Because of this, many comments call for the use of a certificate of analysis in place of analytical testing.

Another comment states some unintended consequences could occur in the industry due to the testing requirements, including stress on the current contract laboratory facilities and in-house laboratories, and also increases in holding costs, due to changes in turn-around time at outside labs. Other comments point to the loss of product choice that could occur if the testing requirements force manufacturers to go out of business or discontinue certain products.

(Response) In response to comments, we have revised the testing requirements in the final rule. We also have revised our estimates of the costs of testing. In what follows, we describe the estimated number and costs of tests required by this final rule.

The final rule requires tests for identity for each incoming shipment lot of dietary ingredient. Estimating the number of tests per batch is complicated, because the tests are required on the shipment lots and we have data only on the number of batches of dietary supplements produced. For example, if a shipment lot of some dietary ingredient is used in six batches of final products, it would need to be tested for identity only once. The number of required identity tests per batch of final product will equal the number of dietary ingredients per batch, divided by the average number of batches per shipment lot (to account for the production of multiple batches of dietary supplements from single lots of components). In addition to the required identity tests, a subset of other components will be tested for identity (these tests are likely to be the responsibility of suppliers and need only be done once per batch no matter how many recipients of those batches).

The quantity and quality of evidence on the variables used to estimate the number of tests varies greatly. In this section, we explain the evidence and assumptions we used to construct the formulas for the number of tests.

Number of dietary ingredients. We based our measure of the number of dietary ingredients per product on a sample of almost 3,000 dietary supplement labels (Ref. E7). Although some ingredients may be missing from the labels and some listed ingredients may be missing from the products, the ingredient list represents the best evidence we have on what ingredients are used in dietary supplements. Although comments claimed that we underestimated the number of ingredients, they offered no evidence that would persuade us to change our estimates, which are based on a sample representing at least 10 percent of the products in the market.

According to the sample of listed ingredients, vitamin and mineral products contain about 13 listed dietary ingredients. Other dietary supplements, mainly herbals, contain about four listed dietary ingredients (Ref. E7).

Number of unlisted components. Dietary supplements are manufactured using solvents, binders, and lubricants that may not show up in the final product. An industry source (Ref. E21) says that four to six unlisted components are typical per product, although fewer are certainly possible. The minimum number is zero. Based on industry data, we assume that the number of unlisted components would be zero to six for vitamins and minerals, and zero to four for herbal and other products.

Number of shipments (i.e., shipment lots) of ingredients and unlisted components. We have no direct information on the number of shipment lots of dietary ingredients and other components. We also have no information on the number of shipments per lot or on the number of shipments per batch. It is costly to store components, so some establishments may buy many small lots of dietary ingredients and other components rather than a few large lots. Crude botanical and other ingredients are inherently unstable and may lose their stability in even a short time unless costly temperature, humidity, and light controls are in place. We also know, however, that some dietary ingredient suppliers produce and ship ingredients in large lots. For dietary supplements produced using part of a large production run of a dietary ingredient, the number of batches per shipment lot could be large. Also, some producers buy a single large shipment lot of a raw material and use it in many batches. We assume that as many as 12 batches per shipment lot of dietary ingredient is a plausible maximum. Based on consultation with industry (Ref. E21), we assumed, in the cost calculation, that 1 was the minimum and 12 the maximum number of batches produced per lot, with 6.5 the average. We received no comments on our use of the assumption in the analysis of the proposed rule and continue to use it in our analysis of the final rule. In the sensitivity analysis, we show how costs change when we change the assumption.

Number of batches produced. We have survey results on the number of batches produced per establishment (Ref. E2). Several comments stated that we underestimated the number of batches produced, which we found to be the case because of an erroneous calculation in the contractor's report. In the revised contract survey results, very small establishments produce an average of 444 (revised from 223) batches per year, small establishments produce an average of 2,436 (revised from 554) batches per year, and large establishments produce an average of 1,164 (revised from 309) batches per year.

Number of final product tests per batch. We have reduced the number of tests required for final products. We assume that establishments will test a representative sample of batches to ensure that the final products meet specifications. We do not specify any particular statistical sampling plan.

Costs per test. We estimate the costs per test partly with published prices of independent laboratories as posted on the Internet (Refs. E22 and E23), and partly from our conversations with FDA and industry experts on testing. Testing costs vary according to frequency and complexity. The more frequently technicians perform tests, the lower are the costs per test. Many tests require sophisticated equipment, such as gas chromatography, high pressure liquid chromatography, distillation, extraction, various spectrophotometers, and other types of equipment. Using sophisticated equipment requires trained personnel. Even simple physical or organoleptic testing requires training or experienced personnel. The type of ingredient, compound, or product can also affect the cost because some are easily identified using routine or single step techniques and others require multiple steps or complex techniques, especially if there are similar products that can be mistaken for the products being identified. The type of defect tested for affects the cost; some defects can be found visually if they are found on the surface, but others are latent. Some tests require multiple samples or multiple steps. In addition, tests require taking and preparing samples, whose cost can vary. By assuming a single distribution for testing costs, we may overestimate testing costs for sectors or products with below-average costs and underestimate testing cost for sectors with above-average costs. In the cost model, for example, we distinguish between botanical ingredients and nonbotanical ingredients in the number of tests, but not in average testing costs. If the average cost of testing botanical products is higher than the average cost for vitamins and minerals, the distribution of costs may underestimate total testing costs for botanical products. We do not have sufficient information

on the range of testing costs for botanical ingredients to determine if the average cost of testing is higher or lower than for other ingredients.

The average cost per test is about $60, based on a range of costs we found on the Internet. This cost represents the full cost of carrying out a test, including collecting and storing the sample, the time for training the personnel who carry out the test, and any associated records. We assume that $20 per test represents a lower bound. Although some Internet prices for tests are as high as $300, we assumed that, with frequent testing, $150 would be a more plausible upper bound average cost. The majority of listed prices fell into the $20 to $80 range, so we selected $50 (the midpoint) as most likely.

The number and cost of tests: Summary. We estimate the number of tests required of the representative manufacturer as a weighted average of the number of tests required for vitamins and minerals and the number of tests required for all other supplements (which were mainly herbal products). The weights, shown as follows, differ by size of manufacturer:

- 24 percent of very small manufacturers produce vitamins and minerals; 76 percent produce other dietary supplements.
- 42 percent of small manufacturers produce vitamins and minerals; 58 percent produce other dietary supplements.
- 69 percent of large manufacturers produce vitamins and minerals; 31 percent produce other dietary supplements.

Most establishments already conduct some tests, or send samples out for testing. We therefore adjusted the estimated testing costs of the final rule to include only required tests and to account for the testing costs currently borne voluntarily by manufacturers. The survey results showed how many respondents were conducting various types of tests.

TABLE 27.—VALUES USED TO ESTIMATE TESTING COSTS

Name	Value or Distribution Used	Source
Number of dietary ingredients per product batch	Vitamins and minerals—13 All other categories—4	Sample from 3,000 dietary supplement labels (Ref. E7)
Number of identity tests per dietary ingredient lot	1 identity test per ingredient lot	Based on requirements of final rule
Number of identity tests per other component lot	1 identity test per subset of component lots	Assumption based on use of certificates of analysis for ingredients
Number of tests for specifications per ingredient lot	1 to 5 tests per subset of ingredient lots	Assumption based on use of certificates of analysis for ingredients
Number of unlisted components	0 to 6 components for vitamins and minerals, 0 to 4 for herbal and other products	Ref. E21
Number of shipments (lots) of ingredients and unlisted components	1 to 12 batches per shipment lot of dietary ingredients	Assumption based on discussions with industry
Number of batches produced per year	Very small establishments–444 Small establishments–2,436 Large–1,164	Ref. E2
Number of final product tests per batch	1 test per subset	Based on requirements of the final rule
Costs per test	Beta pert distribution skewed rightward between $20 and $150; $50 most likely; $60 average	Refs. E22 and E23

(Comment 356) We received comments on labor costs that would be incurred as a result of the 2003 CGMP Proposal. All comments state that personnel costs will increase significantly. One comment states that the average manufacturing wage we used to estimate labor costs, $15.65, does not reflect the true cost of additional labor, since higher skilled employees, such as quality control engineers and, as one comment asserts, Ph.D.-level employees, will need to be hired to comply with the rule. This comment states that, including benefits, the wage actually ranges between $23.28 and $72.00 per hour, depending on skill. Other comments estimate additional annual labor costs ranging between $25,000 and $350,000.

(Response) We used more recent estimates to the average manufacturing wage cost of $26 per hour to estimate the cost of labor (Ref. E24). The comment that asserted Ph.D.-level employees are needed to comply with the rule, provided no basis for this assertion. We disagree that Ph.D.-level workers are needed for the tasks required by this final rule because most of the costs estimated as labor costs all involved ordinary labor tasks such as sanitation, monitoring, and recordkeeping. For more difficult or complicated tasks, more skilled workers may be required, but the overall average labor cost represents the best overall estimate for valuing the average cost of labor in the industry. We assume that various tasks required by the final rule would take some number of hours per year, per batch of product, or per square foot of physical plant.

Estimating costs. We initially gathered information and made assumptions about the full cost of a provision. We then adjusted these estimates to account for the many activities already being carried out, as well other activities that would not have to be carried out by all establishments. We used the survey to estimate the likelihood that an establishment will incur a cost. To get an estimate of the average cost of a provision (adjusted for baseline activities) for each category, we multiply the average cost per establishment by the probability that the

establishment will need to undertake the expense (one minus the probability that the establishment is already doing it). For each provision of the final rule, the simulation carried out the following calculation:
Cost per unit of analysis for each provision =
number of units of analysis per establishment x
probability that establishment incurs cost x
cost per provision per establishment.

We estimate both a setup cost (a one-time fixed cost) of the provision and an annual recurring cost. To get the total costs of the rule, we multiply the number of establishments in each size category (from the survey) by the average costs per establishment in that category. We then adjust for the establishments that did not respond to the survey but are believed to be in the industry. Two hundred thirty-eight establishments responded to the survey; we estimate that 1,566 firms are in the industry, including ingredient suppliers. The number of firms covered by most of the provisions will therefore be about 1,460.

We estimate total costs with the following calculation:
(Number of very small establishments x costs per very small establishment) +
(number of small establishments x costs per small establishment) +
(number of large establishments x costs per large establishment) +
(number of warehouses x costs per warehouse).

The rule is complex and the industry is made up of very different kinds of firms, so cost estimates are averages with, in some cases, large variances. The cost per unit, number of batches and employees, and probability that the establishment would incur the cost all contain uncertainty. The values in table 28 of this document are used in the cost estimates, and are generated from multiple sources.

TABLE 28.—ADDITIONAL VALUES USED IN COST CALCULATIONS

Name	Value or Distribution Used	Source
Average wage per hour	$26	Employment Index, Bureau of Labor Statistics (Ref. E24)
Average size of establishments in square feet	very small = 24,674 small = 71,354 large = 596,000	Ref. E2
Average number of employees	very small = 7.6 small = 95 large = 1,005	Ref. E2
Procedures	8 to 16 hours setup time for small firms; 30 to 40 hours for large firms; annual cost is 10 percent of setup time per provision	Ref. E25
Personnel sanitation	1 hour per week per worker	Assumption, based on requirements of final rule
Sanitation time for physical plant	1 hour per week for very small establishments; costs per small and large plants scaled in proportion to size of plant	Assumption, based on difference in average physical plant size
Sanitation supervisor	1 hour per week	Assumption, based on requirements of final rule
Pest control setup costs	$1,500 to $2,000 for very small establishments; $1,800 to $2,400 for small establishments; $2,600 to $3,400 for large establishments. Average for each size establishment was midpoint ($1,750, $2,100, $3,000)	Ref. E26
Pest control annual costs	$400 to $600 per month for very small establishments; $480 to $720 for small establishments; $700 to $1,000 for large establishments. Average for each size establishment was the midpoint ($500, $600, $850)	Ref. E26
Renovation cost	$50 per square foot; with 0 to 20 percent of physical plant to be renovated, with 10 percent most likely	Based on construction costs and square feet (Ref. E2)
Equipment replacement	For very small establishments, 0 to $1,000; costs per small and large plants scaled in proportion to size of plant	Assumption, based on size of establishments (Ref. E2)
Setup costs for automatic equipment	$500 for hardware, 16 hours	Software costs and assumptions about labor hours
Annual costs for automatic equipment	10 percent of setup costs	Assumption based on requirements of the final rule

TABLE 28.—ADDITIONAL VALUES USED IN COST CALCULATIONS—Continued

Name	Value or Distribution Used	Source
Sanitation of equipment and surfaces	5 hours per week for very small establishments; costs per small and large plants scaled in proportion to size of plant	Assumption based on average sizes of establishments (Ref. E2)
Holding products and dietary ingredients: Capital requirements	Same as costs of equipment upgrades	Based on average sizes of establishments (Ref. E2)
Default probabilities that establishments are not currently acting in accordance with a provision	For very small establishments, 0.2; for small establishments, 0.05, for large establishments, 0.01	Based on results of survey for other practices (Ref. E2)

The total setup costs for this final rule will be $41 million, spread out over the 36 months following the publication date of the final rule. The annual costs, once the final rule is fully implemented, will be $164 million, with the two largest costs being $52 million for testing and $24 million for records. The estimated total cost is the mean of a range of estimates based on the data and assumptions described in tables 27 and 28 of this document. In the uncertainty and sensitivity analyses in section XXIV.B.11 of this document, we show how uncertainty and different assumptions generate higher or lower estimated costs. Using plausible assumptions about the uncertain variables, we estimate that total quantified costs most likely will fall within a range of $104 million to $322 million per year.

8. Summary of Benefits and Costs

We estimate that, once it is fully implemented, the annual quantified benefits from the final rule will be $8 million to $64 million, with a mean estimate of $44 million. However, there are potentially large benefits of the rule that we were not able to quantify. The annual costs will be $104 million to $322 million, with a mean estimate of $164 million. The rule will not be fully effective until 36 months after the publication date. Table 29 of this document shows how the phase-in of the final rule will generate the costs and quantifiable benefits for the first 4 years. Table 30 of this document shows the present and annualized values of costs and quantifiable benefits over 20 years, calculated at discount rates of 3 percent and 7 percent. We have determined, based in part on the analysis presented here, that the benefits, quantified and unquantified, of this final rule justify the costs.

TABLE 29.—COSTS AND QUANTIFIABLE BENEFITS BY YEAR

	1st year	2nd year	3rd year	4th year
Costs (in millions)	$16	$120	$190	$164
Benefits (in millions)	$3	$29	$44	$44

TABLE 30. PRESENT AND ANNUALIZED VALUES OF COSTS AND QUANTIFIABLE BENEFITS

	Present value at 3 percent (in billions)	Present value at 7 percent (in billions)	Annualized Value over 20 years at 3 percent (in millions)	Annualized Value over 20 years at 7 percent (in millions)
Costs	$2.3	$1.6	$153	$149
Benefits	$0.6	$0.4	$40	$39

In table 31 of this document we show the annual costs for each subpart of the regulation. We identify selected costs for particular activities for some of the subparts. We are unable to estimate benefits by subpart, because we estimate the benefits by type of benefit rather than by provision of the final rule.

TABLE 31.—COSTS BY SUBPART

Subpart	Setup Cost (in millions)	Annual Cost (in millions)
A. General provisions	not applicable	not applicable
B. Personnel	$1.5	$15.7
C. Physical plant and grounds	$34.0	$17.4
D. Equipment and utensils	$0.9	$2.3
E. Establish production and process control system Subtotal for identity testing Subtotal for all other testing	$0.5 negligible $0.3	$66.1 $45.0 $ 6.8

TABLE 31.—COSTS BY SUBPART—Continued

Subpart	Setup Cost (in millions)	Annual Cost (in millions)
F. Quality control	negligible	$2.1
G. Components, packaging, labels, and dietary supplements received	negligible	$31.6
H. Master manufacturing record	$0.1	negligible
I. Batch production record	negligible	$5.4
J. Laboratory operations	$0.2	negligible
K. Manufacturing operations	negligible	$2.2
L. Packaging and labeling operations	$0.1	$10.8
M. Holding and distributing	$2.7	$0.5
N. Returned dietary supplements	negligible	$0.2
O. Product complaints	$0.1	$4.5
P. Records and recordkeeping	not applicable	not applicable
Paperwork cost for all subparts	$3.7	$24.2

(Comment 357) We received several comments on the summary of the costs and benefits. In general, the comments state that we overestimated the benefits of the 2003 CGMP Proposal and underestimated the costs. Other comments assert that total estimated benefits of the 2003 CGMP Proposal would not be $216.6 million, as estimated by us, but as low as $13.9 million. Comments also estimate first-year costs as high as $629 million, with annual costs estimated as high as $860 million. Other comments predict product prices will increase, and consumers will decrease consumption of dietary supplements.

(Response) We agree with the comments stating that we underestimated the costs and overestimated the quantified benefits of the 2003 CGMP Proposal. We have increased our estimate of costs in this final rule compared with the estimate in the 2003 CGMP Proposal. We have decreased our estimate of quantified benefits of the final rule compared with the estimate in the 2003 CGMP Proposal. As explained previously, we are unable to quantify all of the benefits of the final rule. These changes in the estimated benefits and costs of this final rule reflect both the changes in the 2003 CGMP Proposal and the changes in our analysis in response to comments.

We agree with the comment that part of the costs of this final rule will be passed on to consumers as higher prices for dietary supplements. The annual costs of this final rule are less than 1 percent of total spending on dietary supplements. We expect that the majority of these costs will be borne by consumers of dietary supplements, who will likely respond to the increase in prices by reducing consumption.

The comments suggesting very high costs and very low benefits did not persuade us that those extreme values were more likely than our estimates. We recognize, however, that the uncertainties in our analysis make a broad range of benefits and costs possible. In the analysis of uncertainty, we will show the range of predicted benefits and costs. We also will show the sensitivity of costs and benefits to certain key assumptions used in the analysis, and how changes in those assumptions can generate the extreme values cited in some comments.

9. Benefits and Costs of Regulatory Options

We considered several regulatory options, including: (1) No new regulatory action, (2) fewer requirements for vitamins and minerals, (3) more restrictive regulations than the final rule, (4) HACCP without the other elements of the final rule, (5) final product testing only, (6) a final rule for high-risk products or hazards only, and (7) the 2003 CGMP Proposal. Although we received no comments on our analysis of the benefits and costs of options 2 through 6, we received many comments on the estimated benefits and costs of the 2003 CGMP Proposal. We have now revised the estimated quantifiable benefits and costs of the 2003 CGMP Proposal. The revised estimates are based on the comments received and the corrections made to the data.

Using the same method as used in this final rule to determine benefits, we estimate that the quantifiable benefits of the 2003 CGMP Proposal would be approximately the same as the quantifiable benefits of the final rule, $44 million per year.

With the corrected estimated number of batches produced, we estimate that the setup costs of the 2003 CGMP Proposal would be $51 million. If the 2003 CGMP Proposal had been finalized, the annual costs of complying with the requirements would be $282 million, or about $118 million more than this final rule. The 2003 CGMP Proposal relied more on testing final products and other controls closer to the end-product. Under the 2003 CGMP Proposal, for example, annual testing costs would be about $97 million.

10. Cost Effectiveness Analysis

Both benefit-cost analysis and cost-effectiveness analysis provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. OMB Circular A–4 requires that major rulemakings be supported by both types of analysis wherever possible. A cost-effectiveness analysis is particularly useful when the primary benefits of the rulemaking are improved public health

and safety.[18] The main advantage of measures of effectiveness are that they account for a rule's impact on morbidity (nonfatal illness, injury, impairment, and quality of life) as well as premature death. The inclusion of morbidity effects is important because some illnesses (e.g., asthma) cause more instances of pain and suffering than they do premature death.

The primary benefits expected to result from this rulemaking are reduced numbers of acute and chronic illnesses and reduced number of recalls involving dietary supplement products. We were not able to quantify chronic illnesses that could be avoided as a result of this rulemaking. We were able to determine that we could avoid about $40 million annually in costs of acute illnesses and $4 million in avoided recalls as a result of improved dietary supplement manufacturing.

We can use the $40 million annually in avoided acute illnesses costs to calculate a cost-effectiveness measure for this rule; $40 million in reduced illness costs translates into 48,662 QALDs saved on an annual basis. Given that the annual costs of this final rule are expected to be $164 million, the cost of each QALD saved is $3,370. This is an overestimate of the cost of a QALD saved because we were unable to quantify the benefits of reduced chronic illness as a result of this rulemaking.

11. Uncertainties in the Analysis

We used indirect measures of the benefits of this final rule which required several key assumptions that are critical for our estimates. With the exception of the recall benefit, which is based directly on our recall records, each component of the estimated benefits involves assumptions that reflect our uncertainty. The estimated costs also embody key assumptions that reflect our uncertainty.

One assumption that affects both estimated costs and estimated benefits is that manufacturing practices in the industry will persist in the absence of additional regulation. If the trend in the market is toward the adoption of more manufacturing controls than we are proposing here, then both the costs and benefits of the rule will be less than we estimate. If the market trend is toward fewer voluntary controls, then both the costs and benefits of the regulation will be greater than we estimate.

In addition to the general assumption about the effects of the rule, we rely on several key assumptions.

We assume there is an average of one reported illness for each class 1 and 2 recall.

The frequency of actual illnesses is 100 times the frequency of reported illnesses. We recognize that there is considerable uncertainty about the factor of 100.

For the baseline estimates, we assume $5 million is the value of a statistical life and $300,000 is the value of a quality-adjusted life year. The estimated health benefits change with changes in those valuations.

Finally, we assume that the reported recalls that occurred from 1990 through 1999 represent the number and type of recalls that would have occurred but for the implementation of this regulation. The cost model also relies on several key assumptions. We assume that single shipment lots of ingredients and unlisted components will be used for many batches of final dietary supplement products. We assume that all testing other than identity testing of incoming ingredients will be done on representative samples. The number of batches or lots tested will be the square root of n + 1, with n equal to the total number of batches or lots.

We also assume that the costs per test, which include the labor costs of selecting the samples and arranging for the tests, will be between $20 and $150, with $50 most likely.

We first characterized the uncertainties as a probability distribution. We ran 5,000 computer simulations to estimate both benefits and costs. The simulations used distributions (given in the tables and the text) in place of point estimates.

TABLE 32.—DISTRIBUTION OF SIMULATION RESULTS FOR ANNUAL BENEFITS AND COSTS

	5th Percentile	Mean	95th Percentile
Annual costs (in millions)	$109	$164	$260
Annual quantified benefits (in millions)	$36	$44	$54

The Monte Carlo computer simulations give the distributions of estimated benefits and costs. If the underlying distributions fully capture the uncertainty of the estimates, then the simulation results give a full picture of the uncertainty. With uncertain distributions used in the simulations, however, the ranges reported in the tables may not fully capture the uncertainties of the analysis. An alternative way to show the uncertainty is to see how sensitive the results are to plausible changes in certain key assumptions. We start with benefits.

For our baseline estimated benefits of this final rule, we use a $5 million value for a statistical life (VSL) and a $300,000 value for a quality-adjusted life year. In the sensitivity analysis, we use values of $3 million for a statistical life and $100,000 for a quality-adjusted life year to generate a ''low'' estimate of health benefits and values of $7 million and $500,000 to generate a ''high'' estimate.

The reporting rate of illnesses associated with dietary supplements is unknown, which makes our estimate of the total number of illnesses highly uncertain. We use 1 percent as the average reporting rate, which implies that total illness are 100 times our estimate of reported illnesses. Although we assume this reporting rate is the most plausible for illnesses associated with dietary supplements, the evidence supporting it is not strong. We show the effects of reporting rates of 2.5 percent and 10 percent.

(Comment 358) Several comments questioned our assumption that the final rule will eliminate the recalls used to estimate benefits.

(Response) We do not assume that all recalls will be eliminated; we only assume that the recalls caused by manufacturing problems identified previously will be eliminated if the rule is fully effective. If the rule is not fully effective, then the quantified benefits will be less than we have estimated. In the following discussion we show the effects of different assumptions about the effectiveness of the final rule.

The quantified benefits depend on the hazards found in recalled products

[18] It should be noted that many of the benefits of this rule are quality benefits that are not quantified and will not be part of this analysis.

between 1990 and 1999. The 69 recalls in 1998 dominate the estimate, accounting for 58 percent of class 1 and class 2 recalls, and 35 percent of all recalls for the decade. In this sensitivity analysis we estimate the effect of excluding 1998 from the data used to estimate average annual benefits. We also consider the effects of using the annual average number of recalls from 2000 through 2005 to estimate benefits.

TABLE 33.—SENSITIVITY OF BENEFITS

Description	Estimated Annual Benefits (after 3 years) (in millions)
Final rule	$44
VSL = $3 million and $/QALY = $100,000 (baselines are $5 million and $300,000)	$24
VSL = $7 million and $/QALY = $500,000 (baselines are $5 million and $300,000)	$64
Each recall represents one illness, with reporting rate of 10 percent (baseline is 1 percent)	$8
Each recall represents one illness, with reporting rate of 2.5 percent (baseline is 1 percent)	$20
Final rule reduces manufacturing recalls by 80 percent (baseline is 100 percent)	$35
Exclude 1998 recalls from estimate, so average annual number of manufacturing recalls is 14 (baseline is 19.5)	$27
Average annual number of manufacturing recalls = 2000–2005 average, so average per year is 10 (baseline is 19.5)	$26

In the sensitivity analysis of annual costs, we change assumptions about the numbers covered by the rule, the number of batches produced per establishment, the number of lots per batch, the average costs per test, and the rate of verification testing.

The number of establishments covered is uncertain because we based it on voluntary survey responses and other evidence from the 1990s. If the number of establishments has increased or decreased, or if our original data overstated or understated the correct number, then the estimated costs will be either too low or too high. We show the effects of different numbers for one arbitrarily lower number covered and one arbitrarily higher number covered.

The number of batches produced is our basic measure of output. Annual costs therefore vary directly with this measure and its components. We show how the costs depend on the number of batches by estimating costs for 50 percent less and 50 percent more batches than estimated from the survey.

The number of shipment lots and the cost per test determine identity testing costs, the single largest contributor to annual costs. We show how the costs vary if the average number of batches per lot is 1 or 12. We vary the average cost per test from $20 to $100.

TABLE 34.—SENSITIVITY OF COSTS

Description	Estimated Annual Cost (after 3 years) (in millions)
Final rule	$164
Number of covered establishments is 1,300 (baseline is 1,460)	$148
Number of covered establishments is 1,600 (baseline is 1,460)	$178
Number of batches are 50 percent of baseline (baseline is 444, 2,436, and 1,164)	$104
Number of batches are 150 percent of baseline (baseline is 444, 2,436, and 1,164)	$224
1 batch of dietary supplements per shipment lot of a dietary ingredient (baseline is 6.5)	$322
12 batches of dietary supplements per shipment lot of a dietary ingredient (baseline is 6.5)	$136
Average cost per test is $20 (baseline is $60)	$129
Average cost per test is $100 (baseline is $60)	$197

We combine the results of the sensitivity analyses to generate overall ranges for benefits and costs. We estimate that, once it is fully implemented, the annual benefits, able to be quantified, from the final rule will be $8 million to $64 million; the annual costs will be $104 million to $322 million.

C. Final Regulatory Flexibility Analysis

1. Introduction

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of

the rule on small entities. We find that this final rule will have a significant economic impact on a substantial number of small entities.

2. Economic Effects on Small Entities

a. *Number of small entities affected.* The final rule will affect many small entities. A small business in this industry is any establishment with fewer than 500 employees. For purposes of the cost-benefit analysis, we also looked at the category we call very small establishments: Establishments with fewer than 20 employees. Based on the survey (Ref. E2), we estimated that 774 establishments, 53 percent of the total establishments, could be classified as very small (under 20 employees) and 526 as small (20 to 499 employees), which is 36 percent of the total establishments. Based on the results of the survey (Ref. E2), we estimated the total number of warehouses, wholesalers, and other holders likely to be covered by this regulation to be 15,689, of which 15,421 are small businesses.

The small establishments that will be affected by the final rule are those establishments that will have to perform the various required activities, and would not have done so without the rule. We determined estimated baseline (pre-CGMP requirements) manufacturing practices with the survey of the industry (Ref. E2). The survey asked representative respondents to answer a series of questions, including how many employees they had and what their existing practices were. From the survey, we determined that small establishments do not now follow all of the provisions of the final rule. Those that do not follow all the applicable provisions will incur a cost to do so.

b. *Costs to small entities.* Implementation costs vary across establishments depending on current practices and the types of products manufactured, packaged, labeled, or held. We estimated the range of current practices using the survey of the industry. The cost model, which we describe in detail in section XXIV.B.7 of this document, divided establishments by size, which allowed us to estimate the distribution of costs per establishment for each size and product class. Table 35 of this document shows the cost per establishment for very small and small establishments. For comparison, we include the estimated average cost per large establishment and the median revenues for each size category. As table 35 of this document shows, costs per establishment are proportionally higher for very small than for large establishments. The table's most striking result is that annual costs are highest for small (20 to 499 employees) establishments.

TABLE 35.—COSTS PER ESTABLISHMENT, BY SIZE

	Setup Costs per Establishment	Annual Costs per Establishment	Median Annual Revenue per Establishment
Very small establishments	$26,000	$46,000	Under $1 million
Small establishments	$20,000	$184,000	$5 to $10 million
Large establishments	$31,000	$69,000	$10 to $50 million
Warehouses, wholesalers, and other holders	$360	$1,000	Not applicable

TABLE 36.—TOTAL COSTS BY ESTABLISHMENT SIZE

	Setup Costs	Percent of Total Setup Costs	Annual Costs	Percent of Total Annual Costs
Very small establishments	$20 million	49 percent	$38 million	23 percent
Small establishments	$10 million	24 percent	$98 million	60 percent
Large establishments	$5 million	12 percent	$11 million	7 percent
Warehouses, wholesalers, and other holders	$6 million	15 percent	$17 million	10 percent

Small establishments that do not perform a substantial number of the actions required by the final rule will bear relatively high costs for compliance with the provisions of this final rule. Although the final rule will raise product prices, the price increase (which would largely be determined by changes made by large establishments) may be much smaller than the increase in the average costs of very small producers. The average burden to very small establishments will be about 4 percent of annual revenue. The average burden to small establishments will be 1.5 to 3 percent of annual revenue. Establishments with above average costs, and even establishments with average costs, could be hard pressed to continue to operate. Some of these may decide it is too costly and either change product lines or go out of business.

We use a model developed under contract by Eastern Research Group to estimate the effects of FDA regulations on small businesses (Ref. E27). The model is designed to assess the effects of a wide range of potential regulatory activities, ranging from HACCP to product labeling. CGMP regulations are included as a potential regulatory activity. The model allows us to predict the probability and frequency of small business failure as a result of our regulations.

We ran the model for the final rule. The model predicts that, as a result of the final rule, 140 very small and 32 small dietary supplement manufacturers will be at risk of going out of business. The model estimates the number of workers in those firms to be about 2,250.

The regulatory costs of this final rule will also discourage new small businesses from entering the industry. The dietary supplement has been characterized by substantial entry of small businesses. Although we cannot quantify how much that will change, we expect that the rate of entry of very small and small businesses will decrease.

3. Regulatory Options

a. *Exemptions for small entities*. The burden on small establishments would be reduced if they were exempt from some provisions of the final rule. Most entities (we estimate close to 90 percent) affected by this final rule, however, are small. Exempting small establishments from some or all of its provisions would substantially reduce benefits.

b. *Longer compliance periods*. Lengthening the compliance period provides some regulatory relief for businesses with fewer than 500 employees. The longer compliance period will allow additional time for setting up recordkeeping, making capital improvements to the physical plant, purchasing new or replacement equipment, and other one-time expenditures. It will also delay the impact of the annual costs of compliance. We have given businesses with fewer than 20 employees an additional 24 months and businesses with fewer than 500 but 20 or more employees an additional 12 months for compliance. The final rule, then, will be phased-in over 36 months, with firms with 500 or more employees complying after 12 months, firms with under 500 but 20 or more employees after 24 months, and firms with fewer than 20 employees after 36 months. The cost savings of delay may well be larger than simply the present value of the delay because the firms with fewer than 500 employees may also be able to reduce their compliance costs by taking advantage of increases in industry knowledge and experience in implementing these regulations.

c. *Reduced requirements in the final rule*. The modification of requirements in this final rule, compared with the 2003 CGMP Proposal, significantly reduce the costs borne by small businesses. We estimate the average setup costs under the 2003 CGMP Proposal to be $25,000 for very small establishments and $40,000 for small establishments. We estimate that the annual costs of the 2003 CGMP Proposal would be $90,000 for very small establishments and $300,000 for small establishments. The final rule therefore reduces annual costs for very small establishments to about half of the estimated costs of the proposed rule and reduces costs for very small establishments to about 60 percent of the estimated costs of the 2003 CGMP Proposal. Under the 2003 CGMP Proposal, 216 very small and 50 small businesses would be at risk of going out of business, over 50 percent more than under the final rule.

4. Description of Recordkeeping and Reporting

The Regulatory Flexibility Act requires a description of the recordkeeping and reporting required for compliance with this final rule. This final rule will require the preparation of records. As described in the 2003 CGMP Proposal, Preliminary Regulatory Impact Analysis, written records or electronic documents must be kept that demonstrate that specific actions occurred in the manufacturing process in compliance with the final rule. Records that will be required in this final rule will demonstrate that corrective actions were taken; that equipment, instruments, and controls used in laboratory operations and quality control were installed and calibrated properly; that maintenance programs were followed; and that the results of any testing show that components or dietary supplements meet the established specifications.

The compliance cost of recordkeeping is the sum of both the initial design and printing of the recordkeeping documents and the recurring costs of maintaining the records. The cost of training personnel to use the new documents is a recurring cost depending on how frequently documents are modified, how often personnel turn over, and how complicated the tasks are that are being recorded. The recurring costs are measured by the workers' wage rate multiplied by the expected labor hours necessary for a written or electronic record and the time necessary for management to review the records to see that actions are documented accurately. In addition, electronic records necessitate recurring time spent ensuring that the equipment is serviced and maintained properly.

5. Summary

The final rule will have a significant economic impact on a substantial number of small entities.

(Comment 359) We received many comments on the 2003 CGMP Proposal Preliminary Regulatory Flexibility Analysis. Nearly all of the comments addressing small business state that the requirements of the 2003 CGMP Proposal, the testing requirements in particular, would be an enormous burden on small business. Other comments assert that, because of this burden, the rule is in violation of the Regulatory Flexibility Act. In addition, comments assert small business will be particularly burdened by the rule and that consumers will see little improvement in product safety as a result.

Some small firms estimate annual testing costs for the 2003 CGMP Proposal as high as $600,000, as opposed to the $60,000 per year estimated by us. Another firm estimates setup costs in the range of 4 to 7 times our estimate and annual costs 8 to 30 times our estimate. Comments also express concern that we have underestimated the number of businesses forced to close if this rule is made final as proposed; one comment states that the rule would cause 50 percent of small businesses to shut down. Some comments assert that this rule is anti-competitive: That is, the comments claim that this rule will make dietary supplement manufacturing so expensive that only large companies will survive. In addition, a few comments note the loss of product choice, innovation, and domestic employment that accompany firm closures, in addition to the increase in prices of products made by remaining firms. In addition, another comment suggests that foreign manufacturers will be at an advantage because they will not have to comply with the rule's requirements.

Some comments reiterate the points made earlier that the use of statistical sampling and supplier certificates of analysis could help reduce the burden on small business.

One comment states that it would be extremely costly for small firms to come into compliance with the 2003 CGMP Proposal, especially because, as several firms pointed out, small firms often produce batches that are small in size. A few comments, however, say that small firms should be made to comply with the new rule at the same time as large firms.

We received many comments on the compliance period of this rule. Some of these comments favor the extended compliance periods granted to small and very small firms. Other comments do not support the compliance periods, stating that they are not long enough for firms to set up recordkeeping systems, make capital improvements, and so on.

Other comments do not favor granting small firms more time to comply. Three comments state that granting small firms a longer compliance period defeats the purpose of the rule, by making it difficult for consumers to determine which dietary supplements comply with the CGMPs and which do not yet comply. Another comment suggests that products made by firms not in compliance 1 year after the rule's effective date be labeled to say, ''This product may not conform to government standards for purity and potency.''

Other comments propose a single compliance period for all firms.

(Response) We disagree with comments that the burden of this final rule violates the Regulatory Flexibility Act. The act requires agencies to consider the burden of their regulatory proposals on small entities, analyze and consider effective alternatives that reduce the burden on small entities, and make their analyses available for public comment. We have considered the burden of this final rule on all covered firms, including small businesses, and as a result have modified certain requirements to reduce the costs of the final rule as compared with the 2003 CGMP Proposal. In addition, small businesses are allowed more time to comply with the rule. The burden on small businesses remains large, but the Regulatory Flexibility Act does not require agencies to adopt regulations that impose the least burden on small entities. In addition, the Data Quality Act has been fulfilled by using the most objective data available. In this analysis, we used data from surveys and from other Federal agencies. Although more data are desirable, we consider the quality of the data used in this analysis and in the references to be the best available and sufficient to fulfill the requirements of the Regulatory Flexibility and Data Quality Acts.

We have reduced the amount of testing required in this final rule in response to comments on the burden of testing costs on the 2003 CGMP Proposal. As explained in Section XXIV.B.7 of this document, we underestimated costs in the proposed rule because of an error in a contractor's report. We have corrected the cost calculations, including estimated testing costs, for this final regulatory flexibility analysis.

We note that foreign firms that sell dietary supplements in the United States are required to be in compliance with the final rule.

In response to comments on the number of firms likely to go out of business, we have used our small business model to estimate that 172 small and very small firms will be at risk of going out of business. Many other small firms—some of them already experiencing financial difficulties–may see their financial condition worsen as a result of this final rule.

We disagree with the comments that oppose longer compliance periods for small businesses. The additional time will only slightly delay the full implementation (and full benefits) of this final rule, and may provide the margin of survival for some small businesses.

D. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The current (2005) inflation-adjusted statutory threshold is $122 million. This final rule qualifies as a significant rule under the statute. Most of the requirements of the Unfunded Mandates are fulfilled in the Executive Order 12866 analysis. The requirements under the Unfunded Mandates Reform Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

The future costs from the rule are the recurring costs, which reach their long-term value in the third year after the effective date of this rule. These costs would be incurred, directly or indirectly, by the establishments that manufacture, process, pack, label, transport, distribute, receive, hold, or import dietary supplements or ingredients. Recurring costs from the regulatory requirements will be incurred in each future year. Table 29 of this document summarizes the annual future recurring costs.

The costs, direct and indirect, of the rule will be shared among manufacturers, processors, packagers, transporters, receivers, holders, and importers of dietary supplements or ingredients, as well as domestic consumers. Much of the higher costs incurred by domestic suppliers of dietary supplement products as a result of these regulations will be passed on to consumers as higher prices. The higher prices will be offset by the benefits from these regulations.

Although this final regulation is significant, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The dietary supplement industry is too small a part of the domestic economy to influence overall economic activity.

This final rule will require additional controls throughout the production and distribution chain for the manufacture of dietary supplements. The additional costs will increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be partly passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of U.S. exports could reduce the quantity of U.S. exports demanded, particularly in comparison with exports from countries that do not implement similar regulations. We expect this effect to be insignificant, because under the final rule the increases in the price of U.S. exports (and resulting decreases in quantity demanded) will be quite small.

XXV. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXVI. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Furthermore, we did not receive any comments from States or their representative organizations regarding to our analysis of the proposed rule regarding the principles set forth in Executive Order 13132. Accordingly, we conclude that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XXVII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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List of Subjects in 21 CFR Part 111

Dietary foods, Drugs, Foods, Packaging and containers.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA is amending 21 CFR chapter I by adding part 111 to read as follows:

PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

Subpart A—General Provisions

Subpart B—Personnel

Subpart C—Physical Plant and Grounds

Subpart D—Equipment and Utensils

Subpart E—Requirement to Establish a Production and Process Control System

Authority: 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

Subpart A—General Provisions

§ 111.1 Who is subject to this part?

(a) Except as provided by paragraph (b) of this section, you are subject to this part if you manufacture, package, label, or hold a dietary supplement, including:

(1) A dietary supplement you manufacture but that is packaged or labeled by another person; and

(2) A dietary supplement imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) The requirements pertaining to holding dietary supplements do not apply to you if you are holding those dietary supplements at a retail establishment for the sole purpose of direct retail sale to individual consumers. A retail establishment does not include a warehouse or other storage facility for a retailer or a warehouse or other storage facility that sells directly to individual consumers.

§ 111.3 What definitions apply to this part?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to such terms when used in this part. For the purpose of this part, the following definitions also apply:

Actual yield means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular dietary supplement.

Batch means a specific quantity of a dietary supplement that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.

Batch number, lot number, or control number means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, and/or holding of a batch or lot of dietary supplements can be determined.

Component means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients (as described in section 201(ff) of the act) and other ingredients.

Contact surface means any surface that contacts a component or dietary supplement, and those surfaces from which drainage onto the component or dietary supplement, or onto surfaces that contact the component or dietary supplement, occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, contact surfaces of equipment, and packaging.

Ingredient means any substance that is used in the manufacture of a dietary supplement and that is intended to be present in the finished batch of the dietary supplement. An ingredient includes, but is not necessarily limited to, a dietary ingredient as defined in section 201(ff) of the act.

In-process material means any material that is fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the manufacture of a dietary supplement.

Lot means a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications for identity, purity, strength, and composition; or, in the case of a dietary supplement produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.

Microorganisms means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes species that:

(1) May have public health significance;

(2) May cause a component or dietary supplement to decompose;

(3) Indicate that the component or dietary supplement is contaminated with filth; or

(4) Otherwise may cause the component or dietary supplement to be adulterated.

Must is used to state a requirement.

Pest means any objectionable insect or other animal including birds, rodents, flies, mites, and larvae.

Physical plant means all or any part of a building or facility used for or in connection with manufacturing, packaging, labeling, or holding a dietary supplement.

Product complaint means any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a dietary supplement, that could be related to current good manufacturing practice. Examples of product complaints are: Foul odor, off taste, illness or injury, disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a dietary supplement container, improper packaging, mislabeling, or dietary supplements that are superpotent, subpotent, or contain the wrong ingredient, or contain a drug or other contaminant (e.g., bacteria, pesticide, mycotoxin, glass, lead).

Quality means that the dietary supplement consistently meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act.

Quality control means a planned and systematic operation or procedure for ensuring the quality of a dietary supplement.

Quality control personnel means any person, persons, or group, within or outside of your organization, who you designate to be responsible for your quality control operations.

Representative sample means a sample that consists of an adequate number of units that are drawn based on rational criteria, such as random sampling, and that are intended to ensure that the sample accurately portrays the material being sampled.

Reprocessing means using, in the manufacture of a dietary supplement, clean, uncontaminated components or dietary supplements that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a dietary supplement.

Reserve sample means a representative sample of product that is held for a designated period of time.

Sanitize means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.

Theoretical yield means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular dietary supplement, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

Water activity (a_w) is a measure of the free moisture in a component or dietary supplement and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

We means the U.S. Food and Drug Administration (FDA).

You means a person who manufactures, packages, labels, or holds dietary supplements.

§ 111.5 Do other statutory provisions and regulations apply?

In addition to this part, you must comply with other applicable statutory provisions and regulations under the act related to dietary supplements.

Subpart B—Personnel

§ 111.8 What are the requirements under this subpart B for written procedures?

You must establish and follow written procedures for fulfilling the requirements of this subpart.

§ 111.10 What requirements apply for preventing microbial contamination from sick or infected personnel and for hygienic practices?

(a) *Preventing microbial contamination.* You must take measures to exclude from any operations any person who might be a source of microbial contamination, due to a health condition, where such contamination may occur, of any material, including components, dietary supplements, and contact surfaces used in the manufacture, packaging, labeling, or holding of a dietary supplement. Such measures include the following:

(1) Excluding from working in any operations that may result in contamination any person who, by medical examination, the person's

acknowledgement, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, dietary supplements, or contact surfaces, until the health condition no longer exists; and

(2) Instructing your employees to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that could result in microbial contamination of any components, dietary supplements, or any contact surface.

(b) *Hygienic practices.* If you work in an operation during which adulteration of the component, dietary supplement, or contact surface could occur, you must use hygienic practices to the extent necessary to protect against such contamination of components, dietary supplements, or contact surfaces. These hygienic practices include the following:

(1) Wearing outer garments in a manner that protects against the contamination of components, dietary supplements, or any contact surface;

(2) Maintaining adequate personal cleanliness;

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with microorganisms) in an adequate hand-washing facility:

(i) Before starting work; and

(ii) At any time when the hands may have become soiled or contaminated;

(4) Removing all unsecured jewelry and other objects that might fall into components, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods in which components or dietary supplements are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against contamination of components, dietary supplements, or contact surfaces;

(5) Maintaining gloves used in handling components or dietary supplements in an intact, clean, and sanitary condition. The gloves must be of an impermeable material;

(6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;

(7) Not storing clothing or other personal belongings in areas where components, dietary supplements, or any contact surfaces are exposed or where contact surfaces are washed;

(8) Not eating food, chewing gum, drinking beverages, or using tobacco products in areas where components, dietary supplements, or any contact surfaces are exposed, or where contact surfaces are washed; and

(9) Taking any other precautions necessary to protect against the contamination of components, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

§ 111.12 What personnel qualification requirements apply?

(a) You must have qualified employees who manufacture, package, label, or hold dietary supplements.

(b) You must identify who is responsible for your quality control operations. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations.

(c) Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person's assigned functions.

§ 111.13 What supervisor requirements apply?

(a) You must assign qualified personnel to supervise the manufacturing, packaging, labeling, or holding of dietary supplements.

(b) Each supervisor whom you use must be qualified by education, training, or experience to supervise.

§ 111.14 Under this subpart B, what records must you make and keep?

(a) You must make and keep records required under this subpart B in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart B; and

(2) Documentation of training, including the date of the training, the type of training, and the person(s) trained.

Subpart C—Physical Plant and Grounds

§ 111.15 What sanitation requirements apply to your physical plant and grounds?

(a) *Grounds.* You must keep the grounds of your physical plant in a condition that protects against the contamination of components, dietary supplements, or contact surfaces. The methods for adequate ground maintenance include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical plant so that it does not attract pests, harbor pests, or provide pests a place for breeding;

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed;

(3) Adequately draining areas that may contribute to the contamination of components, dietary supplements, or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests;

(4) Adequately operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed; and

(5) If your plant grounds are bordered by grounds not under your control, and if those other grounds are not maintained in the manner described in this section, you must exercise care in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous materials that may be a source of contamination.

(b) *Physical plant facilities.* (1) You must maintain your physical plant in a clean and sanitary condition; and

(2) You must maintain your physical plant in repair sufficient to prevent components, dietary supplements, or contact surfaces from becoming contaminated.

(c) *Cleaning compounds, sanitizing agents, pesticides, and other toxic materials.* (1) You must use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and that are safe and adequate under the conditions of use.

(2) You must not use or hold toxic materials in a physical plant in which components, dietary supplements, or contact surfaces are manufactured or exposed, unless those materials are necessary as follows:

(i) To maintain clean and sanitary conditions;

(ii) For use in laboratory testing procedures;

(iii) For maintaining or operating the physical plant or equipment; or

(iv) For use in the plant's operations.

(3) You must identify and hold cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials in a manner that

protects against contamination of components, dietary supplements, or contact surfaces.

(d) *Pest control.* (1) You must not allow animals or pests in any area of your physical plant. Guard or guide dogs are allowed in some areas of your physical plant if the presence of the dogs will not result in contamination of components, dietary supplements, or contact surfaces;

(2) You must take effective measures to exclude pests from the physical plant and to protect against contamination of components, dietary supplements, and contact surfaces on the premises by pests; and

(3) You must not use insecticides, fumigants, fungicides, or rodenticides, unless you take precautions to protect against the contamination of components, dietary supplements, or contact surfaces.

(e) *Water supply.* (1) You must provide water that is safe and sanitary, at suitable temperatures, and under pressure as needed, for all uses where water does not become a component of the dietary supplement.

(2) Water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface, must, at a minimum, comply with applicable Federal, State, and local requirements and not contaminate the dietary supplement.

(f) *Plumbing.* The plumbing in your physical plant must be of an adequate size and design and be adequately installed and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from your physical plant;

(3) Avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(5) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.

(g) *Sewage disposal.* You must dispose of sewage into an adequate sewage system or through other adequate means.

(h) *Bathrooms.* You must provide your employees with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not be a potential source of contamination to components, dietary supplements, or contact surfaces.

(i) *Hand-washing facilities.* You must provide hand-washing facilities that are designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(j) *Trash disposal.* You must convey, store, and dispose of trash to:

(1) Minimize the development of odors;

(2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;

(3) Protect against contamination of components, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant; and

(4) Control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.

(k) *Sanitation supervisors.* You must assign one or more employees to supervise overall sanitation. Each of these supervisors must be qualified by education, training, or experience to develop and supervise sanitation procedures.

§ 111.16 What are the requirements under this subpart C for written procedures?

You must establish and follow written procedures for cleaning the physical plant and for pest control.

§ 111.20 What design and construction requirements apply to your physical plant?

Any physical plant you use in the manufacture, packaging, labeling, or holding of dietary supplements must:

(a) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations;

(b) Have adequate space for the orderly placement of equipment and holding of materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mixups of components and dietary supplements during manufacturing, packaging, labeling, or holding;

(c) Permit the use of proper precautions to reduce the potential for mixups or contamination of components, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. Your physical plant must have, and you must use, separate or defined areas of adequate size or other control systems, such as computerized inventory controls or automated systems of separation, to prevent contamination and mixups of components and dietary supplements during the following operations:

(1) Receiving, identifying, holding, and withholding from use, components, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, labeling, or holding of dietary supplements;

(2) Separating, as necessary, components, dietary supplements, packaging, and labels that are to be used in manufacturing from components, dietary supplements, packaging, or labels that are awaiting material review and disposition decision, reprocessing, or are awaiting disposal after rejection;

(3) Separating the manufacturing, packaging, labeling, and holding of different product types including different types of dietary supplements and other foods, cosmetics, and pharmaceutical products;

(4) Performing laboratory analyses and holding laboratory supplies and samples;

(5) Cleaning and sanitizing contact surfaces;

(6) Packaging and label operations; and

(7) Holding components or dietary supplements.

(d) Be designed and constructed in a manner that prevents contamination of components, dietary supplements, or contact surfaces.

(1) The design and construction must include:

(i) Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair;

(ii) Fixtures, ducts, and pipes that do not contaminate components, dietary supplements, or contact surfaces by dripping or other leakage, or condensate;

(iii) Adequate ventilation or environmental control equipment such as airflow systems, including filters, fans, and other air-blowing equipment, that minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate components, dietary supplements, or contact surfaces;

(iv) Equipment that controls temperature and humidity, when such equipment is necessary to ensure the quality of the dietary supplement; and

(v) Aisles or working spaces between equipment and walls that are adequately

unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, dietary supplements, or contact surfaces with clothing or personal contact.

(2) When fans and other air-blowing equipment are used, such fans and equipment must be located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, dietary supplements, or contact surfaces;

(e) Provide adequate light in:

(1) All areas where components or dietary supplements are examined, processed, or held;

(2) All areas where contact surfaces are cleaned; and

(3) Hand-washing areas, dressing and locker rooms, and bathrooms.

(f) Use safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials when the light bulbs, fixtures, skylights or other glass or glass-like materials are suspended over exposed components or dietary supplements in any step of preparation, unless your physical plant is otherwise constructed in a manner that will protect against contamination of components or dietary supplements in case of breakage of glass or glass-like materials.

(g) Provide effective protection against contamination of components and dietary supplements in bulk fermentation vessels, by, for example:

(1) Use of protective coverings;

(2) Placement in areas where you can eliminate harborages for pests over and around the vessels;

(3) Placement in areas where you can check regularly for pests, pest infestation, filth or any other extraneous materials; and

(4) Use of skimming equipment.

(h) Use adequate screening or other protection against pests, where necessary.

§ 111.23 Under this subpart C, what records must you make and keep?

(a) You must make and keep records required under this subpart C in accordance with subpart P of this part.

(b) You must make and keep records of the written procedures for cleaning the physical plant and for pest control.

(c) You must make and keep records that show that water, when used in a manner such that the water may become a component of the dietary supplement, meets the requirements of § 111.15(e)(2).

Subpart D—Equipment and Utensils

§ 111.25 What are the requirements under this subpart D for written procedures?

You must establish and follow written procedures for fulfilling the requirements of this subpart D, including written procedures for:

(a) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement;

(b) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and

(c) Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements.

§ 111.27 What requirements apply to the equipment and utensils that you use?

(a) You must use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.

(1) Equipment and utensils include the following:

(i) Equipment used to hold or convey;

(ii) Equipment used to measure;

(iii) Equipment using compressed air or gas;

(iv) Equipment used to carry out processes in closed pipes and vessels; and

(v) Equipment used in automated, mechanical, or electronic systems.

(2) You must use equipment and utensils of appropriate design and construction so that use will not result in the contamination of components or dietary supplements with:

(i) Lubricants;

(ii) Fuel;

(iii) Coolants;

(iv) Metal or glass fragments;

(v) Filth or any other extraneous material;

(vi) Contaminated water; or

(vii) Any other contaminants.

(3) All equipment and utensils you use must be:

(i) Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces;

(ii) Corrosion-resistant if the equipment or utensils contact components or dietary supplements;

(iii) Made of nontoxic materials;

(iv) Designed and constructed to withstand the environment in which they are used, the action of components or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and

(v) Maintained to protect components and dietary supplements from being contaminated by any source.

(4) Equipment and utensils you use must have seams that are smoothly bonded or maintained to minimize accumulation of dirt, filth, organic material, particles of components or dietary supplements, or any other extraneous materials or contaminants.

(5) Each freezer, refrigerator, and other cold storage compartment you use to hold components or dietary supplements:

(i) Must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that indicates and records, or allows for recording by hand, the temperature accurately within the compartment; and

(ii) Must have an automated device for regulating temperature or an automated alarm system to indicate a significant temperature change in a manual operation.

(6) Instruments or controls used in the manufacturing, packaging, labeling, or holding of a dietary supplement, and instruments or controls that you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), water activity, or other conditions, to control or prevent the growth of microorganisms or other contamination must be:

(i) Accurate and precise;

(ii) Adequately maintained; and

(iii) Adequate in number for their designated uses.

(7) Compressed air or other gases you introduce mechanically into or onto a component, dietary supplement, or contact surface or that you use to clean any contact surface must be treated in such a way that the component, dietary supplement, or contact surface is not contaminated.

(b) You must calibrate instruments and controls you use in manufacturing or testing a component or dietary supplement. You must calibrate:

(1) Before first use;

(2) At the frequency specified in writing by the manufacturer of the instrument and control; or

(3) At routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument and control.

(c) You must repair or replace instruments or controls that cannot be adjusted to agree with the reference standard.

(d) You must maintain, clean, and sanitize, as necessary, all equipment, utensils, and any other contact surfaces used to manufacture, package, label, or hold components or dietary supplements.

(1) Equipment and utensils must be taken apart as necessary for thorough maintenance, cleaning, and sanitizing.

(2) You must ensure that all contact surfaces, used for manufacturing or holding low-moisture components or dietary supplements, are in a dry and sanitary condition when in use. When the surfaces are wet-cleaned, they must be sanitized, when necessary, and thoroughly dried before subsequent use.

(3) If you use wet processing during manufacturing, you must clean and sanitize all contact surfaces, as necessary, to protect against the introduction of microorganisms into components or dietary supplements. When cleaning and sanitizing is necessary, you must clean and sanitize all contact surfaces before use and after any interruption during which the contact surface may have become contaminated. If you use contact surfaces in a continuous production operation or in consecutive operations involving different batches of the same dietary supplement, you must adequately clean and sanitize the contact surfaces, as necessary.

(4) You must clean surfaces that do not come into direct contact with components or dietary supplements as frequently as necessary to protect against contaminating components or dietary supplements.

(5) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be:

(i) Stored in appropriate containers; and

(ii) Handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary supplements, or any contact surface.

(6) Cleaning compounds and sanitizing agents must be adequate for their intended use and safe under their conditions of use;

(7) You must store cleaned and sanitized portable equipment and utensils that have contact surfaces in a location and manner that protects them from contamination.

§ 111.30 What requirements apply to automated, mechanical, or electronic equipment?

For any automated, mechanical, or electronic equipment that you use to manufacture, package, label, or hold a dietary supplement, you must:

(a) Design or select equipment to ensure that dietary supplement specifications are consistently met;

(b) Determine the suitability of the equipment by ensuring that your equipment is capable of operating satisfactorily within the operating limits required by the process;

(c) Routinely calibrate, inspect, or check the equipment to ensure proper performance. Your quality control personnel must periodically review these calibrations, inspections, or checks;

(d) Establish and use appropriate controls for automated, mechanical, and electronic equipment (including software for a computer controlled process) to ensure that any changes to the manufacturing, packaging, labeling, holding, or other operations are approved by quality control personnel and instituted only by authorized personnel; and

(e) Establish and use appropriate controls to ensure that the equipment functions in accordance with its intended use. These controls must be approved by quality control personnel.

§ 111.35 Under this subpart D, what records must you make and keep?

(a) You must make and keep records required under this subpart D in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart, including written procedures for:

(i) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement;

(ii) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and

(iii) Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements;

(2) Documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment, unless such documentation is kept with the batch record;

(3) Documentation of any calibration, each time the calibration is performed, for instruments and controls that you use in manufacturing or testing a component or dietary supplement. In your documentation, you must:

(i) Identify the instrument or control calibrated;

(ii) Provide the date of calibration;

(iii) Identify the reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy;

(iv) Identify the calibration method used, including appropriate limits for accuracy and precision of instruments and controls when calibrating;

(v) Provide the calibration reading or readings found;

(vi) Identify the recalibration method used, and reading or readings found, if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and

(vii) Include the initials of the person who performed the calibration and any recalibration.

(4) Written records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment;

(5) Backup file(s) of current software programs (and of outdated software that is necessary to retrieve records that you are required to keep in accordance with subpart P of this part, when current software is not able to retrieve such records) and of data entered into computer systems that you use to manufacture, package, label, or hold dietary supplements.

(i) Your backup file (e.g., a hard copy of data you have entered, diskettes, tapes, microfilm, or compact disks) must be an exact and complete record of the data you entered.

(ii) You must keep your backup software programs and data secure from alterations, inadvertent erasures, or loss; and

(6) Documentation of the controls that you use to ensure that equipment functions in accordance with its intended use.

Subpart E—Requirement to Establish a Production and Process Control System

§ 111.55 What are the requirements to implement a production and process control system?

You must implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

§ 111.60 What are the design requirements for the production and process control system?

(a) Your production and in-process control system must be designed to ensure that the dietary supplement is manufactured, packaged, labeled, and held in a manner that will ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record; and

(b) The production and in-process control system must include all requirements of subparts E through L of this part and must be reviewed and approved by quality control personnel.

§ 111.65 What are the requirements for quality control operations?

You must implement quality control operations in your manufacturing, packaging, labeling, and holding operations for producing the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

§ 111.70 What specifications must you establish?

(a) You must establish a specification for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

(b) For each component that you use in the manufacture of a dietary supplement, you must establish component specifications as follows:

(1) You must establish an identity specification;

(2) You must establish component specifications that are necessary to ensure that specifications for the purity, strength and composition of dietary supplements manufactured using the components are met; and

(3) You must establish limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement.

(c) For the in-process production:

(1) You must establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplements and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement;

(2) You must provide adequate documentation of your basis for why meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the specifications are met for the identity, purity, strength, and composition of the dietary supplements and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement; and

(3) Quality control personnel must review and approve the documentation that you provide under paragraph (c)(2) of this section.

(d) You must establish specifications for dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications). Packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of the dietary supplement.

(e) For each dietary supplement that you manufacture you must establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement.

(f) If you receive a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must establish specifications to provide sufficient assurance that the product you receive is adequately identified and is consistent with your purchase order.

(g) You must establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements, including specifications that ensure that you used the specified packaging and that you applied the specified label.

§ 111.73 What is your responsibility for determining whether established specifications are met?

You must determine whether the specifications you establish under § 111.70 are met.

§ 111.75 What must you do to determine whether specifications are met?

(a) Before you use a component, you must:

(1) Conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient; and

(2) Confirm the identity of other components and determine whether other applicable component specifications established in accordance with § 111.70(b) are met. To do so, you must either:

(i) Conduct appropriate tests or examinations; or

(ii) Rely on a certificate of analysis from the supplier of the component that you receive, provided that:

(A) You first qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations;

(B) The certificate of analysis includes a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations;

(C) You maintain documentation of how you qualified the supplier;

(D) You periodically re-confirm the supplier's certificate of analysis; and

(E) Your quality control personnel review and approve the documentation setting forth the basis for qualification (and re-qualification) of any supplier.

(b) You must monitor the in-process points, steps, or stages where control is necessary to ensure the quality of the finished batch of dietary supplement to:

(1) Determine whether the in-process specifications are met; and

(2) Detect any deviation or unanticipated occurrence that may result in a failure to meet specifications.

(c) For a subset of finished dietary supplement batches that you identify through a sound statistical sampling plan (or for every finished batch), you must verify that your finished batch of the dietary supplement meets product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or that may lead to adulteration of the finished batch of the dietary supplement. To do so:

(1) You must select one or more established specifications for identity, purity, strength, composition, and the limits on those types of contamination that may adulterate or that may lead to adulteration of the dietary supplement that, if tested or examined on the finished batches of the dietary supplement, would verify that the production and process control system is producing a dietary supplement that meets all product specifications (or only those product specifications not otherwise exempted from this provision by quality control personnel under paragraph (d) of this section);

(2) You must conduct appropriate tests or examinations to determine compliance with the specifications selected in paragraph (c)(1) of this section;

(3) You must provide adequate documentation of your basis for determining compliance with the specification(s) selected under paragraph (c)(1) of this section, through the use of appropriate tests or examinations conducted under paragraph (c)(2) of this section, will ensure that your finished batch of the dietary supplement meets all product specifications for identity, purity, strength, and composition, and the limits on those types of contamination that may adulterate, or that may lead to

the adulteration of, the dietary supplement; and

(4) Your quality control personnel must review and approve the documentation that you provide under paragraph (c)(3) of this section.

(d)(1) You may exempt one or more product specifications from verification requirements in paragraph (c)(1) of this section if you determine and document that the specifications you select under paragraph (c)(1) of this section for determination of compliance with specifications are not able to verify that the production and process control system is producing a dietary supplement that meets the exempted product specification and there is no scientifically valid method for testing or examining such exempted product specification at the finished batch stage. In such a case, you must document why, for example, any component and in-process testing, examination, or monitoring, and any other information, will ensure that such exempted product specification is met without verification through periodic testing of the finished batch; and

(2) Your quality control personnel must review and approve the documentation that you provide under paragraph (d)(1) of this section.

(e) Before you package or label a product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must visually examine the product and have documentation to determine whether the specifications that you established under § 111.70 (f) are met.

(f)(1) Before you use packaging, you must, at a minimum, conduct a visual identification of the containers and closures and review the supplier's invoice, guarantee, or certification to determine whether the packaging specifications are met; and

(2) Before you use labels, you must, at a minimum, conduct a visual examination of the label and review the supplier's invoice, guarantee, or certification to determine whether label specifications are met.

(g) You must, at a minimum, conduct a visual examination of the packaging and labeling of the finished packaged and labeled dietary supplements to determine whether you used the specified packaging and applied the specified label.

(h)(1) You must ensure that the tests and examinations that you use to determine whether the specifications are met are appropriate, scientifically valid methods.

(2) The tests and examinations that you use must include at least one of the following:

(i) Gross organoleptic analysis;

(ii) Macroscopic analysis;

(iii) Microscopic analysis;

(iv) Chemical analysis; or

(v) Other scientifically valid methods.

(i) You must establish corrective action plans for use when an established specification is not met.

§ 111.77 What must you do if established specifications are not met?

(a) For specifications established under § 111.70(a), (b)(2), (b)(3), (c), (d), (e), and (g) that you do not meet, quality control personnel, in accordance with the requirements in subpart F of this part, must reject the component, dietary supplement, package or label unless such personnel approve a treatment, an in-process adjustment, or reprocessing that will ensure the quality of the finished dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. No finished batch of dietary supplements may be released for distribution unless it complies with § 111.123(b).

(b) For specifications established under § 111.70(b)(1) that you do not meet, quality control personnel must reject the component and the component must not be used in manufacturing the dietary supplement.

(c) For specifications established under § 111.70(f) that you do not meet, quality control personnel must reject the product and the product may not be packaged or labeled for distribution as a dietary supplement.

§ 111.80 What representative samples must you collect?

The representative samples that you must collect include:

(a) Representative samples of each unique lot of components, packaging, and labels that you use to determine whether the components, packaging, and labels meet specifications established in accordance with § 111.70(b) and (d), and as applicable, § 111.70(a) (and, when you receive components, packaging, or labels from a supplier, representative samples of each unique shipment, and of each unique lot within each unique shipment);

(b) Representative samples of in-process materials for each manufactured batch at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record where control is necessary to ensure the identity, purity, strength, and composition of dietary supplements to determine whether the in-process materials meet specifications established in accordance with § 111.70(c), and as applicable, § 111.70(a);

(c) Representative samples of a subset of finished batches of each dietary supplement that you manufacture, which you identify through a sound statistical sampling plan (or otherwise every finished batch), before releasing for distribution to verify that the finished batch of dietary supplement meets product specifications established in accordance with § 111.70(e), and as applicable, § 111.70(a);

(d) Representative samples of each unique shipment, and of each unique lot within each unique shipment, of product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) to determine whether the received product meets specifications established in accordance with § 111.70(f), and as applicable, § 111.70(a); and

(e) Representative samples of each lot of packaged and labeled dietary supplements to determine whether the packaging and labeling of the finished packaged and labeled dietary supplements meet specifications established in accordance with § 111.70(g), and as applicable, § 111.70(a).

§ 111.83 What are the requirements for reserve samples?

(a) You must collect and hold reserve samples of each lot of packaged and labeled dietary supplements that you distribute.

(b) The reserve samples must:

(1) Be held using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which it is distributed for packaging and labeling elsewhere;

(2) Be identified with the batch, lot, or control number;

(3) Be retained for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve sample, for use in appropriate investigations; and

(4) Consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the dietary supplement meets product specifications.

§ 111.87 Who conducts a material review and makes a disposition decision?

Quality control personnel must conduct all required material reviews and make all required disposition decisions.

§ 111.90 What requirements apply to treatments, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification established in accordance with § 111.70 is not met?

(a) You must not reprocess a rejected dietary supplement or treat or provide an in-process adjustment to a component, packaging, or label to make it suitable for use in the manufacture of a dietary supplement unless:

(1) Quality control personnel conduct a material review and make a disposition decision to approve the reprocessing, treatment, or in-process adjustment; and

(2) The reprocessing, treatment, or in-process adjustment is permitted by § 111.77;

(b) You must not reprocess any dietary supplement or treat or provide an in-process adjustment to a component to make it suitable for use in the manufacture of a dietary supplement, unless:

(1) Quality control personnel conduct a material review and make a disposition decision that is based on a scientifically valid reason and approves the reprocessing, treatment, or in-process adjustment; and

(2) The reprocessing, treatment or in-process adjustment is permitted by § 111.77;

(c) Any batch of dietary supplement that is reprocessed, that contains components that you have treated, or to which you have made in-process adjustments to make them suitable for use in the manufacture of the dietary supplement must be approved by quality control personnel and comply with § 111.123(b) before releasing for distribution.

§ 111.95 Under this subpart E, what records must you make and keep?

(a) You must make and keep records required under this subpart E in accordance with subpart P of this part.

(b) Under this subpart E, you must make and keep the following records:

(1) The specifications established;

(2) Documentation of your qualification of a supplier for the purpose of relying on the supplier's certificate of analysis;

(3) Documentation for why meeting in-process specifications, in combination with meeting component specifications, helps ensure that the dietary supplement meets the specifications for identity, purity, strength, and composition; and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement; and

(4) Documentation for why the results of appropriate tests or examinations for the product specifications selected under § 111.75(c)(1) ensure that the dietary supplement meets all product specifications;

(5) Documentation for why any component and in-process testing, examination, or monitoring, and any other information, will ensure that a product specification that is exempted under § 111.75(d) is met without verification through periodic testing of the finished batch, including documentation that the selected specifications tested or examined under § 111.75 (c)(1) are not able to verify that the production and process control system is producing a dietary supplement that meets the exempted product specification and there is no scientifically valid method for testing or examining such exempted product specification at the finished batch stage.

Subpart F—Production and Process Control System: Requirements for Quality Control

§ 111.103 What are the requirements under this subpart F for written procedures?

You must establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing.

§ 111.105 What must quality control personnel do?

Quality control personnel must ensure that your manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. To do so, quality control personnel must perform operations that include:

(a) Approving or rejecting all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a dietary supplement;

(b) Reviewing and approving the documentation setting forth the basis for qualification of any supplier;

(c) Reviewing and approving the documentation setting forth the basis for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition of the dietary supplement are met;

(d) Reviewing and approving the documentation setting forth the basis for why the results of appropriate tests or examinations for each product specification selected under § 111.75(c)(1) will ensure that the finished batch of the dietary supplement meets product specifications;

(e) Reviewing and approving the basis and the documentation for why any product specification is exempted from the verification requirements in § 111.75(c)(1), and for why any component and in-process testing, examination, or monitoring, or other methods will ensure that such exempted product specification is met without verification through periodic testing of the finished batch;

(f) Ensuring that required representative samples are collected;

(g) Ensuring that required reserve samples are collected and held;

(h) Determining whether all specifications established under § 111.70(a) are met; and

(i) Performing other operations required under this subpart.

§ 111.110 What quality control operations are required for laboratory operations associated with the production and process control system?

Quality control operations for laboratory operations associated with the production and process control system must include:

(a) Reviewing and approving all laboratory control processes associated with the production and process control system;

(b) Ensuring that all tests and examinations required under § 111.75 are conducted; and

(c) Reviewing and approving the results of all tests and examinations required under § 111.75.

§ 111.113 What quality control operations are required for a material review and disposition decision?

(a) Quality control personnel must conduct a material review and make a disposition decision if:

(1) A specification established in accordance with § 111.70 is not met;

(2) A batch deviates from the master manufacturing record, including when any step established in the master manufacturing record is not completed and including any deviation from specifications;

(3) There is any unanticipated occurrence during the manufacturing

operations that adulterates or may lead to adulteration of the component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record;

(4) Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch or batches of a dietary supplement; or

(5) A dietary supplement is returned.

(b)(1) When there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to adulteration of a component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record, quality control personnel must reject the component, dietary supplement, packaging, or label unless it approves a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence.

(2) When a specification established in accordance with § 111.70 is not met, quality control personnel must reject the component, dietary supplement, package or label, unless quality control personnel approve a treatment, an in-process adjustment, or reprocessing, as permitted in § 111.77.

(c) The person who conducts a material review and makes the disposition decision must, at the time of performance, document that material review and disposition decision.

§ 111.117 What quality control operations are required for equipment, instruments, and controls?

Quality control operations for equipment, instruments, and controls must include:

(a) Reviewing and approving all processes for calibrating instruments and controls;

(b) Periodically reviewing all records for calibration of instruments and controls;

(c) Periodically reviewing all records for calibrations, inspections, and checks of automated, mechanical, or electronic equipment; and

(d) Reviewing and approving controls to ensure that automated, mechanical, or electronic equipment functions in accordance with its intended use.

§ 111.120 What quality control operations are required for components, packaging, and labels before use in the manufacture of a dietary supplement?

Quality control operations for components, packaging, and labels before use in the manufacture of a dietary supplement must include:

(a) Reviewing all receiving records for components, packaging, and labels;

(b) Determining whether all components, packaging, and labels conform to specifications established under § 111.70 (b) and (d);

(c) Conducting any required material review and making any required disposition decision;

(d) Approving or rejecting any treatment and in-process adjustments of components, packaging, or labels to make them suitable for use in the manufacture of a dietary supplement; and

(e) Approving, and releasing from quarantine, all components, packaging, and labels before they are used.

§ 111.123 What quality control operations are required for the master manufacturing record, the batch production record, and manufacturing operations?

(a) Quality control operations for the master manufacturing record, the batch production record, and manufacturing operations must include:

(1) Reviewing and approving all master manufacturing records and all modifications to the master manufacturing records;

(2) Reviewing and approving all batch production-related records;

(3) Reviewing all monitoring required under subpart E;

(4) Conducting any required material review and making any required disposition decision;

(5) Approving or rejecting any reprocessing;

(6) Determining whether all in-process specifications established in accordance with § 111.70(c) are met;

(7) Determining whether each finished batch conforms to product specifications established in accordance with § 111.70(e); and

(8) Approving and releasing, or rejecting, each finished batch for distribution, including any reprocessed finished batch.

(b) Quality control personnel must not approve and release for distribution:

(1) Any batch of dietary supplement for which any component in the batch does not meet its identity specification;

(2) Any batch of dietary supplement, including any reprocessed batch, that does not meet all product specifications established in accordance with § 111.70(e);

(3) Any batch of dietary supplement, including any reprocessed batch, that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act; and

(4) Any product received from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for which sufficient assurance is not provided to adequately identify the product and to determine that the product is consistent with your purchase order.

§ 111.127 What quality control operations are required for packaging and labeling operations?

Quality control operations for packaging and labeling operations must include:

(a) Reviewing the results of any visual examination and documentation to ensure that specifications established under § 111.70(f) are met for all products that you receive for packaging and labeling as a dietary supplement (and for distribution rather than for return to the supplier);

(b) Approving, and releasing from quarantine, all products that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) before they are used for packaging or labeling;

(c) Reviewing and approving all records for packaging and label operations;

(d) Determining whether the finished packaged and labeled dietary supplement conforms to specifications established in accordance with § 111.70(g);

(e) Conducting any required material review and making any required disposition decision;

(f) Approving or rejecting any repackaging of a packaged dietary supplement;

(g) Approving or rejecting any relabeling of a packaged and labeled dietary supplement; and

(h) Approving for release, or rejecting, any packaged and labeled dietary supplement (including a repackaged or relabeled dietary supplement) for distribution.

§ 111.130 What quality control operations are required for returned dietary supplements?

Quality control operations for returned dietary supplements must include:

(a) Conducting any required material review and making any required disposition decision; including:

(1) Determining whether tests or examination are necessary to determine compliance with product specifications established in accordance with § 111.70(e); and

(2) Reviewing the results of any tests or examinations that are conducted to determine compliance with product specifications established in accordance with § 111.70(e);

(b) Approving or rejecting any salvage and redistribution of any returned dietary supplement;

(c) Approving or rejecting any reprocessing of any returned dietary supplement; and

(d) Determining whether the reprocessed dietary supplement meets product specifications and either approving for release, or rejecting, any returned dietary supplement that is reprocessed.

§ 111.135 What quality control operations are required for product complaints?

Quality control operations for product complaints must include reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings and followup action of any investigation performed.

§ 111.140 Under this subpart F, what records must you make and keep?

(a) You must make and keep the records required under this subpart F in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision and written procedures for approving or rejecting any reprocessing;

(2) Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:

(i) Date that the review, approval, or rejection was performed; and

(ii) Signature of the person performing the review, approval, or rejection; and

(3) Documentation of any material review and disposition decision and followup. Such documentation must be included in the appropriate batch production record and must include:

(i) Identification of the specific deviation or the unanticipated occurrence;

(ii) Description of your investigation into the cause of the deviation from the specification or the unanticipated occurrence;

(iii) Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the dietary supplement or a failure to package and label the dietary supplement as specified in the master manufacturing record;

(iv) Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or the unanticipated occurrence;

(v) Explanation of what you did with the component, dietary supplement, packaging, or label;

(vi) A scientifically valid reason for any reprocessing of a dietary supplement that is rejected or any treatment or in-process adjustment of a component that is rejected; and

(vii) The signature of the individual(s) designated to perform the quality control operation, who conducted the material review and made the disposition decision, and of each qualified individual who provides information relevant to that material review and disposition decision.

Subpart G—Production and Process Control System: Requirements for Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling as a Dietary Supplement

§ 111.153 What are the requirements under this subpart G for written procedures?

You must establish and follow written procedures for fulfilling the requirements of this subpart G.

§ 111.155 What requirements apply to components of dietary supplements?

(a) You must visually examine each immediate container or grouping of immediate containers in a shipment that you receive for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the components;

(b) You must visually examine the supplier's invoice, guarantee, or certification in a shipment you receive to ensure the components are consistent with your purchase order;

(c) You must quarantine components before you use them in the manufacture of a dietary supplement until:

(1) You collect representative samples of each unique lot of components (and, for components that you receive, of each unique shipment, and of each unique lot within each unique shipment);

(2) Quality control personnel review and approve the results of any tests or examinations conducted on components; and

(3) Quality control personnel approve the components for use in the manufacture of a dietary supplement, including approval of any treatment (including in-process adjustments) of components to make them suitable for use in the manufacture of a dietary supplement, and releases them from quarantine.

(d)(1) You must identify each unique lot within each unique shipment of components that you receive and any lot of components that you produce in a manner that allows you to trace the lot to the supplier, the date received, the name of the component, the status of the component (e.g., quarantined, approved, or rejected); and to the dietary supplement that you manufactured and distributed.

(2) You must use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of components that you receive and any lot of components that you produce.

(e) You must hold components under conditions that will protect against contamination and deterioration, and avoid mixups.

§ 111.160 What requirements apply to packaging and labels received?

(a) You must visually examine each immediate container or grouping of immediate containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the packaging and labels.

(b) You must visually examine the supplier's invoice, guarantee, or certification in a shipment to ensure that the packaging or labels are consistent with your purchase order.

(c) You must quarantine packaging and labels before you use them in the manufacture of a dietary supplement until:

(1) You collect representative samples of each unique shipment, and of each unique lot within each unique shipment, of packaging and labels and, at a minimum, conduct a visual identification of the immediate containers and closures;

(2) Quality control personnel review and approve the results of any tests or examinations conducted on the packaging and labels; and

(3) Quality control personnel approve the packaging and labels for use in the manufacture of a dietary supplement and release them from quarantine.

(d)(1) You must identify each unique lot within each unique shipment of packaging and labels in a manner that allows you to trace the lot to the supplier, the date received, the name of the packaging and label, the status of the packaging and label (e.g., quarantined, approved, or rejected); and to the dietary supplement that you distributed; and

(2) You must use this unique identifier whenever you record the disposition of each unique lot within

each unique shipment of packaging and labels.

(e) You must hold packaging and labels under conditions that will protect against contamination and deterioration, and avoid mixups.

§ 111.165 What requirements apply to a product received for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier)?

(a) You must visually examine each immediate container or grouping of immediate containers in a shipment of product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the received product.

(b) You must visually examine the supplier's invoice, guarantee, or certification in a shipment of the received product to ensure that the received product is consistent with your purchase order.

(c) You must quarantine the received product until:

(1) You collect representative samples of each unique shipment, and of each unique lot within each unique shipment, of received product;

(2) Quality control personnel review and approve the documentation to determine whether the received product meets the specifications that you established under § 111.70(f); and

(3) Quality control personnel approve the received product for packaging or labeling as a dietary supplement and release the received product from quarantine.

(d)(1) You must identify each unique lot within each unique shipment of received product in a manner that allows you to trace the lot to the supplier, the date received, the name of the received product, the status of the received product (e.g., quarantined, approved, or rejected), and to the product that you packaged or labeled and distributed as a dietary supplement.

(2) You must use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of the received product.

(e) You must hold the received product under conditions that will protect against contamination and deterioration, and avoid mixups.

§ 111.170 What requirements apply to rejected components, packaging, and labels, and to rejected products that are received for packaging or labeling as a dietary supplement?

You must clearly identify, hold, and control under a quarantine system for appropriate disposition any component, packaging, and label, and any product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), that is rejected and unsuitable for use in manufacturing, packaging, or labeling operations.

§ 111.180 Under this subpart G, what records must you make and keep?

(a) You must make and keep records required under this subpart G in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart.

(2) Receiving records (including records such as certificates of analysis, suppliers' invoices, and suppliers' guarantees) for components, packaging, and labels and for products that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier); and

(3) Documentation that the requirements of this subpart were met.

(i) The person who performs the required operation must document, at the time of performance, that the required operation was performed.

(ii) The documentation must include:

(A) The date that the components, packaging, labels, or products that you receive for packaging or labeling as a dietary supplement were received;

(B) The initials of the person performing the required operation;

(C) The results of any tests or examinations conducted on components, packaging, or labels, and of any visual examination of product that you receive for packaging or labeling as a dietary supplement; and

(D) Any material review and disposition decision conducted on components, packaging, labels, or products that you receive for packaging or labeling as a dietary supplement.

Subpart H—Production and Process Control System: Requirements for the Master Manufacturing Record

§ 111.205 What is the requirement to establish a master manufacturing record?

(a) You must prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch.

(b) The master manufacturing record must:

(1) Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record; and

(2) Establish controls and procedures to ensure that each batch of dietary supplement that you manufacture meets the specifications identified in accordance with paragraph (b)(1) of this section.

(c) You must make and keep master manufacturing records in accordance with subpart P of this part.

§ 111.210 What must the master manufacturing record include?

The master manufacturing record must include:

(a) The name of the dietary supplement to be manufactured and the strength, concentration, weight, or measure of each dietary ingredient for each batch size;

(b) A complete list of components to be used;

(c) An accurate statement of the weight or measure of each component to be used;

(d) The identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label and the identity of each ingredient that will be declared on the ingredients list of the dietary supplement;

(e) A statement of any intentional overage amount of a dietary ingredient;

(f) A statement of theoretical yield of a manufactured dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to ensure the quality of the dietary supplement, and the expected yield when you finish manufacturing the dietary supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary and material review is conducted and disposition decision is made;

(g) A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label;

(h) Written instructions, including the following:

(1) Specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and

that the dietary supplement is packaged and labeled as specified in the master manufacturing record;

(2) Procedures for sampling and a cross-reference to procedures for tests or examinations;

(3) Specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

(i) Such specific actions must include verifying the weight or measure of any component and verifying the addition of any component; and

(ii) For manual operations, such specific actions must include:

(A) One person weighing or measuring a component and another person verifying the weight or measure; and

(B) One person adding the component and another person verifying the addition.

(4) Special notations and precautions to be followed; and

(5) Corrective action plans for use when a specification is not met.

Subpart I—Production and Process Control System: Requirements for the Batch Production Record

§ 111.255 What is the requirement to establish a batch production record?

(a) You must prepare a batch production record every time you manufacture a batch of a dietary supplement;

(b) Your batch production record must include complete information relating to the production and control of each batch;

(c) Your batch production record must accurately follow the appropriate master manufacturing record and you must perform each step in the production of the batch; and

(d) You must make and keep batch production records in accordance with subpart P of this part.

§ 111.260 What must the batch record include?

The batch production record must include the following:

(a) The batch, lot, or control number:

(1) Of the finished batch of dietary supplement; and

(2) That you assign in accordance with § 111.415(f) for the following:

(i) Each lot of packaged and labeled dietary supplement from the finished batch of dietary supplement;

(ii) Each lot of dietary supplement, from the finished batch of dietary supplement, that you distribute to another person for packaging or labeling;

(b) The identity of equipment and processing lines used in producing the batch;

(c) The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained;

(d) The unique identifier that you assigned to each component (or, when applicable, to a product that you receive from a supplier for packaging or labeling as a dietary supplement), packaging, and label used;

(e) The identity and weight or measure of each component used;

(f) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(g) The actual results obtained during any monitoring operation;

(h) The results of any testing or examination performed during the batch production, or a cross-reference to such results;

(i) Documentation that the finished dietary supplement meets specifications established in accordance with § 111.70(e) and (g);

(j) Documentation, at the time of performance, of the manufacture of the batch, including:

(1) The date on which each step of the master manufacturing record was performed; and

(2) The initials of the persons performing each step, including:

(i) The initials of the person responsible for weighing or measuring each component used in the batch;

(ii) The initials of the person responsible for verifying the weight or measure of each component used in the batch;

(iii) The initials of the person responsible for adding the component to the batch; and

(iv) The initials of the person responsible for verifying the addition of components to the batch;

(k) Documentation, at the time of performance, of packaging and labeling operations, including:

(1) The unique identifier that you assigned to packaging and labels used, the quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels;

(2) An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record; and

(3) The results of any tests or examinations conducted on packaged and labeled dietary supplements (including repackaged or relabeled dietary supplements), or a cross-reference to the physical location of such results;

(l) Documentation at the time of performance that quality control personnel:

(1) Reviewed the batch production record, including:

(i) Review of any monitoring operation required under subpart E of this part; and

(ii) Review of the results of any tests and examinations, including tests and examinations conducted on components, in-process materials, finished batches of dietary supplements, and packaged and labeled dietary supplements;

(2) Approved or rejected any reprocessing or repackaging; and

(3) Approved and released, or rejected, the batch for distribution, including any reprocessed batch; and

(4) Approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement.

(m) Documentation at the time of performance of any required material review and disposition decision.

(n) Documentation at the time of performance of any reprocessing.

Subpart J—Production and Process Control System: Requirements for Laboratory Operations

§ 111.303 What are the requirements under this subpart J for written procedures?

You must establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met.

§ 111.310 What are the requirements for the laboratory facilities that you use?

You must use adequate laboratory facilities to perform whatever testing and examinations are necessary to determine whether:

(a) Components that you use meet specifications;

(b) In-process specifications are met as specified in the master manufacturing record; and

(c) Dietary supplements that you manufacture meet specifications.

§ 111.315 What are the requirements for laboratory control processes?

You must establish and follow laboratory control processes that are

reviewed and approved by quality control personnel, including the following:

(a) Use of criteria for establishing appropriate specifications;

(b) Use of sampling plans for obtaining representative samples, in accordance with subpart E of this part, of:

(1) Components, packaging, and labels;

(2) In-process materials;

(3) Finished batches of dietary supplements;

(4) Product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier); and

(5) Packaged and labeled dietary supplements.

(c) Use of criteria for selecting appropriate examination and testing methods;

(d) Use of criteria for selecting standard reference materials used in performing tests and examinations; and

(e) Use of test methods and examinations in accordance with established criteria.

§ 111.320 What requirements apply to laboratory methods for testing and examination?

(a) You must verify that the laboratory examination and testing methodologies are appropriate for their intended use.

(b) You must identify and use an appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification is met.

§ 111.325 Under this subpart J, what records must you make and keep?

(a) You must make and keep records required under this subpart J in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met;

(2) Documentation that laboratory methodology established in accordance with this subpart J is followed.

(i) The person who conducts the testing and examination must document, at the time of performance, that laboratory methodology established in accordance with this subpart J is followed.

(ii) The documentation for laboratory tests and examinations must include the results of the testing and examination.

Subpart K—Production and Process Control System: Requirements for Manufacturing Operations

§ 111.353 What are the requirements under this subpart K for written procedures?

You must establish and follow written procedures for manufacturing operations.

§ 111.355 What are the design requirements for manufacturing operations?

You must design or select manufacturing processes to ensure that product specifications are consistently met.

§ 111.360 What are the requirements for sanitation?

You must conduct all manufacturing operations in accordance with adequate sanitation principles.

§ 111.365 What precautions must you take to prevent contamination?

You must take all the necessary precautions during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements. These precautions include:

(a) Performing manufacturing operations under conditions and controls that protect against the potential for growth of microorganisms and the potential for contamination;

(b) Washing or cleaning components that contain soil or other contaminants;

(c) Using water that, at a minimum, complies with the applicable Federal, State, and local requirements and does not contaminate the dietary supplement when the water may become a component of the finished batch of dietary supplement;

(d) Performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated components;

(e) Sterilizing, pasteurizing, freezing, refrigerating, controlling hydrogen-ion concentration (pH), controlling humidity, controlling water activity (a_w), or using any other effective means to remove, destroy, or prevent the growth of microorganisms and prevent decomposition;

(f) Holding components and dietary supplements that can support the rapid growth of microorganisms of public health significance in a manner that prevents the components and dietary supplements from becoming adulterated;

(g) Identifying and holding any components or dietary supplements, for which a material review and disposition decision is required, in a manner that protects components or dietary supplements that are not under a material review against contamination and mixups with those that are under a material review;

(h) Performing mechanical manufacturing steps (such as cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) by any effective means to protect the dietary supplements against contamination, by, for example:

(1) Cleaning and sanitizing contact surfaces;

(2) Using temperature controls; and

(3) Using time controls.

(i) Using effective measures to protect against the inclusion of metal or other foreign material in components or dietary supplements, by, for example:

(1) Filters or strainers,

(2) Traps,

(3) Magnets, or

(4) Electronic metal detectors.

(j) Segregating and identifying all containers for a specific batch of dietary supplements to identify their contents and, when necessary, the phase of manufacturing; and

(k) Identifying all processing lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number and, when necessary, the phase of manufacturing.

§ 111.370 What requirements apply to rejected dietary supplements?

You must clearly identify, hold, and control under a quarantine system for appropriate disposition any dietary supplement that is rejected and unsuitable for use in manufacturing, packaging, or labeling operations.

§ 111.375 Under this subpart K, what records must you make and keep?

(a) You must make and keep records required under this subpart K in accordance with subpart P of this part.

(b) You must make and keep records of the written procedures for manufacturing operations.

Subpart L—Production and Process Control System: Requirements for Packaging and Labeling Operations

§ 111.403 What are the requirements under this subpart L for written procedures?

You must establish and follow written procedures for packaging and labeling operations.

§ 111.410 What requirements apply to packaging and labels?

(a) You must take necessary actions to determine whether packaging for dietary supplements meets specifications so that the condition of the packaging will

ensure the quality of your dietary supplements;

(b) You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies. Label reconciliation is not required for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations; and

(c) You must examine, before packaging and labeling operations, packaging and labels for each batch of dietary supplement to determine whether the packaging and labels conform to the master manufacturing record; and

(d) You must be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution.

§ 111.415 What requirements apply to filling, assembling, packaging, labeling, and related operations?

You must fill, assemble, package, label, and perform other related operations in a way that ensures the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. You must do this using any effective means, including the following:

(a) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary supplement packaging, as appropriate;

(b) Protecting manufactured dietary supplements from contamination, particularly airborne contamination;

(c) Using sanitary handling procedures;

(d) Establishing physical or spatial separation of packaging and label operations from operations on other components and dietary supplements to prevent mixups;

(e) Identifying, by any effective means, filled dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups;

(f) Assigning a batch, lot, or control number to:

(1) Each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement; and,

(2) Each lot of dietary supplement, from a finished batch of dietary supplement, that you distribute to another person for packaging or labeling.

(g) Examining a representative sample of each batch of the packaged and labeled dietary supplement to determine whether the dietary supplement meets specifications established in accordance with § 111.70(g); and

(h) Suitably disposing of labels and packaging for dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

§ 111.420 What requirements apply to repackaging and relabeling?

(a) You may repackage or relabel dietary supplements only after quality control personnel have approved such repackaging or relabeling.

(b) You must examine a representative sample of each batch of repackaged or relabeled dietary supplements to determine whether the repackaged or relabeled dietary supplements meet all specifications established in accordance with § 111.70(g).

(c) Quality control personnel must approve or reject each batch of repackaged or relabeled dietary supplement prior to its release for distribution.

§ 111.425 What requirements apply to a packaged and labeled dietary supplement that is rejected for distribution?

You must clearly identify, hold, and control under a quarantine system for appropriate disposition any packaged and labeled dietary supplement that is rejected for distribution.

§ 111.430 Under this subpart L, what records must you make and keep?

(a) You must make and keep records required under this subpart L in accordance with subpart P of this part.

(b) You must make and keep records of the written procedures for packaging and labeling operations.

Subpart M—Holding and Distributing

§ 111.453 What are the requirements under this subpart for M written procedures?

You must establish and follow written procedures for holding and distributing operations.

§ 111.455 What requirements apply to holding components, dietary supplements, packaging, and labels?

(a) You must hold components and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and dietary supplements are not affected.

(b) You must hold packaging and labels under appropriate conditions so that the packaging and labels are not adversely affected.

(c) You must hold components, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary supplements, packaging, and labels.

§ 111.460 What requirements apply to holding in-process material?

(a) You must identify and hold in-process material under conditions that protect against mixup, contamination, and deterioration.

(b) You must hold in-process material under appropriate conditions of temperature, humidity, and light.

§ 111.465 What requirements apply to holding reserve samples of dietary supplements?

(a) You must hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. This includes:

(1) Holding the reserve samples under conditions consistent with product labels or, if no storage conditions are recommended on the label, under ordinary storage conditions; and

(2) Using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which you distribute the dietary supplement for packaging and labeling elsewhere.

(b) You must retain reserve samples for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples, for use in appropriate investigations.

§ 111.470 What requirements apply to distributing dietary supplements?

You must distribute dietary supplements under conditions that will protect the dietary supplements against contamination and deterioration.

§ 111.475 Under this subpart M, what records must you make and keep?

(a) You must make and keep records required under this subpart M in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for holding and distributing operations; and

(2) Records of product distribution.

Subpart N—Returned Dietary Supplements

§ 111.503 What are the requirements under this subpart N for written procedures?

You must establish and follow written procedures to fulfill the requirements of this subpart.

§ 111.510 What requirements apply when a returned dietary supplement is received?

You must identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision.

§ 111.515 When must a returned dietary supplement be destroyed, or otherwise suitably disposed of?

You must destroy, or otherwise suitably dispose of, any returned dietary supplement unless the outcome of a material review and disposition decision is that quality control personnel do the following:

(a) Approve the salvage of the returned dietary supplement for redistribution or

(b) Approve the returned dietary supplement for reprocessing.

§ 111.520 When may a returned dietary supplement be salvaged?

You may salvage a returned dietary supplement only if quality control personnel conduct a material review and make a disposition decision to allow the salvage.

§ 111.525 What requirements apply to a returned dietary supplement that quality control personnel approve for reprocessing?

(a) You must ensure that any returned dietary supplements that are reprocessed meet all product specifications established in accordance with § 111.70(e); and

(b) Quality control personnel must approve or reject the release for distribution of any returned dietary supplement that is reprocessed.

§ 111.530 When must an investigation be conducted of your manufacturing processes and other batches?

If the reason for a dietary supplement being returned implicates other batches, you must conduct an investigation of your manufacturing processes and each of those other batches to determine compliance with specifications.

§ 111.535 Under this subpart N, what records must you make and keep?

(a) You must make and keep records required under this subpart N in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart N.

(2) Any material review and disposition decision on a returned dietary supplement;

(3) The results of any testing or examination conducted to determine compliance with product specifications established under § 111.70(e); and,

(4) Documentation of the reevaluation by quality control personnel of any dietary supplement that is reprocessed and the determination by quality control personnel of whether the reprocessed dietary supplement meets product specifications established in accordance with § 111.70(e).

Subpart O—Product Complaints

§ 111.553 What are the requirements under this subpart O for written procedures?

You must establish and follow written procedures to fulfill the requirements of this subpart O.

§ 111.560 What requirements apply to the review and investigation of a product complaint?

(a) A qualified person must:

(1) Review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of this part 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury; and

(2) Investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of this part, including those specifications and other requirements that, if not met, may result in a risk of illness or injury.

(b) Quality control personnel must review and approve decisions about whether to investigate a product complaint and review and approve the findings and followup action of any investigation performed.

(c) The review and investigation of the product complaint by a qualified person, and the review by quality control personnel about whether to investigate a product complaint, and the findings and followup action of any investigation performed, must extend to all relevant batches and records.

§ 111.570 Under this subpart O, what records must you make and keep?

(a) You must make and keep the records required under this subpart O in accordance with subpart P of this part.

(b) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart,

(2) A written record of every product complaint that is related to good manufacturing practice,

(i) The person who performs the requirements of this subpart must document, at the time of performance, that the requirement was performed.

(ii) The written record of the product complaint must include the following:

(A) The name and description of the dietary supplement;

(B) The batch, lot, or control number of the dietary supplement, if available;

(C) The date the complaint was received and the name, address, or telephone number of the complainant, if available;

(D) The nature of the complaint including, if known, how the product was used;

(E) The reply to the complainant, if any; and

(F) Findings of the investigation and followup action taken when an investigation is performed.

Subpart P—Records and Recordkeeping

§ 111.605 What requirements apply to the records that you make and keep?

(a) You must keep written records required by this part for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records.

(b) Records must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records.

(c) All electronic records must comply with part 11 of this chapter.

§ 111.610 What records must be made available to FDA?

(a) You must have all records required under this part, or copies of such records, readily available during the retention period for inspection and copying by FDA when requested.

(b) If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA.

Dated: May 8, 2007.

Andrew C. von Eschenbach,

Commissioner of Food and Drugs.

Dated: May 8, 2007.

Michael O. Leavitt,

Secretary of Health and Human Services.

[FR Doc. 07–3039 Filed 6–22–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 2007N–0186]

RIN 0910–AB88

Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule (IFR) that sets forth a procedure for requesting an exemption from the requirement in the final rule ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,'' published elsewhere in this issue of the **Federal Register**, that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met and establishes a requirement for retention of records relating to the FDA's response to an exemption request.

DATES: This rule is effective August 24, 2007.

Compliance Dates: The compliance date is June 25, 2008; except that for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009; and except that for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010.

Submit written or electronic comments by September 24, 2007.

Submit comments regarding information collection by July 25, 2007, to OMB (see **ADDRESSES**).

ADDRESSES: You may submit comments, identified by Docket No. 2007N–0186, and/or RIN number 0910–AB88, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Vasilios Frankos, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1696.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing a final rule establishing current good manufacturing practice requirements (CGMPs) for dietary supplements elsewhere in this issue of the **Federal Register** (hereinafter referred to as the CGMP final rule). The CGMP final rule establishes the minimum CGMPs necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Dietary ingredients are the central defining ingredients of a dietary supplement. Because of the critical importance of ensuring the proper identity of dietary ingredients, we are requiring in the CGMP final rule that each manufacturer perform its own testing or examination (identity testing) to verify the identity of each dietary ingredient prior to use in the manufacturing process. This identity testing requirement applies to a manufacturer who purchases a dietary ingredient from a dietary ingredient supplier or who manufactures its own dietary ingredient for use in the manufacture of its dietary supplement. This requirement for 100 percent identity testing of dietary ingredients is found at Subpart E—Requirement to Establish a Production and Process Control System, § 111.75 ''What must you do to determine whether specifications are met?'' in the CGMP final rule. Section 111.75(a)(1) (21 CFR 111.75(a)(1)) of the CGMP final rule requires (a) Before you use a component, you must: (1) Conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient * * * *.

This provision is discussed at length in section X of the CGMP final rule, published elsewhere in this issue of the **Federal Register**, particularly in the discussions relating to comments submitted in response to the 2003 CGMP proposed rule (68 FR 12157, March 13, 2003) (see the responses to Comments 145 and 174).

Section 111.75(a)(1) of the CGMP final rule reflects our determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution

of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we decided to add to § 111.75(a)(1), an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the agency for such an exemption to 100 percent identity testing under § 10.30 and the agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements.

We also include a requirement to ensure that the manufacturer keeps the FDA's response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95 (21 CFR 111.95).

We did not include this exemption procedure in the CGMP final rule because we wanted to provide an opportunity for interested persons to comment on whether this exemption procedure should be modified, and if so, whether there is any additional information that may be helpful to articulate with respect to what a petition needs to show that may inform future guidance. We believe, based on comments to the proposed rule, that some manufacturers may have already developed internal processes or methods, that involve less than 100 percent identity testing, to ensure the identity of dietary ingredients. For example, some comments recommended that the frequency of testing requirements, in general, be established using a statistically valid method and that the extent of testing be reduced taking into account the history of the supplier. Other comments mentioned the use of vendor audits. Therefore, we did consider the possibility of alternatives to the requirement of 100 percent identity testing of dietary ingredients in the CGMP final rule. We chose to issue this IFR to provide an opportunity to obtain additional comment on an exemption process (see the Comments section of this document). We also determined that the manufacturer's opportunity to collect data to establish such an assurance should not be delayed until a decision on whether the exemption procedure set forth in this IFR should be modified.

Our legal authority for the provision in § 111.75(a)(1)(i) and (a)(1)(ii), and the provision in § 111.95(b)(6), set forth in the following paragraph, is the same as that used in the CGMP final rule. Therefore, we incorporate by reference the discussion of our legal authority for the CGMP final rule (section V of the CGMP final rule) in this IFR.

II. Discussion and Description of Amendments to §§ 111.75 and 111.95

In this IFR we are announcing amendments to the CGMP final rule, published elsewhere in this **Federal Register**. We redesignate § 111.75(a)(1) as § 111.75(a)(1)(i) and set forth a procedure for submission of a petition to FDA in a new § 111.75(a)(1)(ii), under which manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The codified provision set forth in this IFR clarifies that FDA is willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use. For example, the level of continued testing at a rate less than 100 percent should provide the statistical confidence that the probability of receiving a dietary ingredient that does not meet the established specifications for identity is less than a small chosen percentage at a statistical confidence level, e.g., 95 percent. The petition must set forth proposed alternative testing for identity while an exemption is in effect. If FDA grants the petition, the manufacturer must conduct the tests and examinations for the dietary ingredient, otherwise required under § 111.75(a)(1)(i), under the terms specified by FDA when the petition is granted.

If this IFR is not modified, we would consider a manufacturer's request for an exemption from the testing required by § 111.75(a)(1) of the CGMP final rule once the compliance date for that manufacturer (based on the varying compliance dates based on size of the firm, as in the CGMP final rule) passes (see the **DATES** section of this document). In the interim, a manufacturer who may want to request such an exemption, could gather the data and information it needs to support a petition for exemption under § 111.75(a)(1)(ii).

The petition would need to set forth the scientific rationale, and must be accompanied by the supporting data and information, for the proposed alternative testing that will demonstrate that there is no material diminution of assurance, compared to the assurance provided by 100 percent identity testing, of the identity of the dietary ingredient before use in manufacturing a dietary supplement product when the dietary ingredient is obtained from one or more suppliers identified in the petition. We would consider such a petition under § 10.30 (21 CFR 10.30), the citizen petition process. Generally, § 10.30 requires your petition to include:

- The action requested (i.e., a request for an exemption from the requirements of § 111.75(a)(1)(i));
- A statement of grounds;
- A section on environmental impact, including either a claim for categorical exclusion under § 25.30 (21 CFR 25.30) or 21 CFR 25.32 or an environmental assessment under 21 CFR 25.40;
- A statement certifying that, to the best of your knowledge and belief, your petition includes all information and views on which the petition relies, and that it includes representative data and information known to you which are unfavorable to the petition.

You should identify any information in the petition that you consider to be confidential commercial or trade secret information and you should segregate such information from other information in your petition. Information in a petition for exemption under § 111.75(a)(1)(ii) that is confidential or trade secret information is not available for public disclosure (21 CFR 20.61). However, that would not preclude the agency from considering such information, such as that about a particular supplier's reliability, when it considers whether to grant or deny other petitions for exemption from 100 percent identity testing from other manufacturers. For example, other manufacturers may use the same supplier as a source of the same dietary ingredient.

If the petition is granted, § 111.75(a)(1)(i) would require the manufacturer to implement the system identified in the petition, which would include the scientific method developed by the manufacturer that would provide data demonstrating that less than 100 percent identity testing did not materially diminish assurance that the dietary ingredient is the correct dietary ingredient. If the petition is granted by FDA, the exemption from the requirement of 100 percent identity testing in § 111.75(a)(1) would apply to the specific dietary ingredient, and any of its attributes (see discussion in section X.G.2 of the CGMP final rule), and the specific dietary ingredient

supplier or suppliers as provided in the petition.[1] The manufacturer would be responsible for documenting the tests and examinations for the dietary ingredient under the terms specified by FDA when the petition is granted, and must make and keep such records under § 111.325 (21 CFR 111.325).

When we review a manufacturer's petition requesting an exemption from the requirement of 100 percent identity testing, we will consider taking into account other data and information that we may have—for example, from other manufacturers who use the same supplier—in order to reduce the 100 percent identity testing requirements applicable to the particular dietary ingredient from the particular supplier. Relevant information from other sources may assist in the determination made on the manufacturer's request for exemption. FDA may request additional data and information from the manufacturer to assist in the review of the petition.

At this juncture, dietary supplement manufacturers are best positioned to develop a system to ensure dietary ingredient identity, according to their particular specifications, that they can use to determine what reduced frequency of testing can be appropriately substituted for 100 percent identity testing. The manufacturer may decide that such a system could include gathering evidence of consistency of analytical results of the dietary ingredient within an acceptable range over a period of time through a history of 100 percent identity testing by the manufacturer, along with evidence that the period of time accurately reflects the range of variability of each specific incoming ingredient (e.g., it would capture variability caused by diverse factors and also would accurately reflect the prevalence of ''errors,'' i.e., incorrect ingredients, in the incoming ingredient shipment lots). All sources of variability and ''error'' in incoming product should be identified and documented. It is important to the public health to ensure that the dietary ingredient, intended to be the dietary ingredient in the finished dietary supplement, is in fact the dietary ingredient used in the manufacture of the dietary supplement.

[1] The identity of the dietary ingredient may include more than one attribute (see discussion in section X.G.2 of the CGMP final rule). For example, identity may include physical characteristics (such as crystal or powder), state of hydration, or part of the plant (roots or leaves). The term ''identity'' would include the manufacturer's specification(s) that would identify the attributes a supplier must meet.

FDA will issue guidance on the information and type of data it recommends be included in the citizen petition. We will issue guidance on what such a petition should contain and how it would be processed. The guidance will include our recommendations about the type of information that a manufacturer could obtain about each supplier that it intends to use for the ingredient and its specifications that would assist us in evaluating the petition.

The approval of an exemption petition will be only for the dietary ingredient(s) and supplier(s) stated in the petition and/or FDA's approval, under the circumstances outlined in the petition. Manufacturers may use one petition to request an exemption from 100 percent identity testing for one or more dietary ingredients and one or more suppliers; however, the petition needs to provide data and information that are specific to each dietary ingredient and each supplier. If the manufacturer changes dietary ingredient(s) or supplier(s), or any other combination thereof, FDA's approval would not apply to the particular changed dietary ingredient (including the supplier of that ingredient). FDA's approval also would not apply to any dietary ingredient(s) for which the supplier(s) has been changed. In these circumstances, the manufacturer would have to resume 100 percent identity testing of the dietary ingredient so affected. However, the manufacturer would not have to necessarily resume 100 percent identity testing for other dietary ingredients, approved in the same petition, that are not changed, and for which suppliers are not changed. Further, if at any time the verification testing conducted by the manufacturer, under the terms of the approved petition, results in the identification of an ingredient that is not the correct dietary ingredient, the FDA approval for that dietary ingredient and supplier would no longer be in effect and the manufacturer would have to return to 100 percent identity testing until such time as it could re-petition of a new exemption. If the manufacturer holding an approved petition becomes aware of information suggesting a change in the nature or quality of the supplier(s) (e.g., change in ownership or management) or of the dietary ingredient(s) (e.g., change in the source of the dietary ingredient) that may affect the identity of the dietary ingredient, the manufacturer should consult with FDA as to whether the approved petition remains in effect or whether the manufacturer should resume 100 percent identity testing.

In addition, we are adding a new paragraph (b)(6) to § 111.95. The agency's response to a petition would be a record of the manufacturer's Production and Process Control System that the manufacturer must retain under § 111.95. Current § 111.95 *Under this subpart, what records must you make and keep?* requires that you must make and keep records required under this subpart in accordance with subpart P. The new paragraph (b)(6) added by this IFR requires that a manufacturer keep FDA's response to a petition submitted under § 111.75(a)(1)(ii) as a record.

III. Final Regulatory Flexibility Analysis

A. Final Regulatory Impact Analysis

FDA has examined the economic impacts of the IFR under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this IFR is not an economically significant regulatory action as defined by Executive Order 12866.

1. Need for Regulation

Elsewhere in this issue of the **Federal Register**, FDA published a final rule, ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' (the CGMP final rule). The CGMP final rule sets forth the manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, labeled, or held in a manner that will ensure the quality of the dietary supplements during manufacturing, packaging, labeling, or holding operations.

Under § 111.75(a)(1), the CGMP final rule requires the manufacturer of a dietary supplement to conduct at least one appropriate test or examination on every incoming lot to verify the identity of any component that is a dietary ingredient before it is used in the manufacture of a dietary supplement.

This IFR modifies § 111.75(a)(1) and renumbers it as § 111.75(a)(1)(i) and adds § 111.75(a)(1)(ii). Section 111.75(a)(1)(i) requires what is in § 111.75(a)(1) of the CGMP final rule, but adds the following exception, ''unless you petition the agency under paragraph (a)(1)(ii) of this section and the agency exempts you from such testing.'' We will use the term ''testing'' in this analysis to refer to either testing or examination of incoming ingredients, whichever is appropriate.

Section 111.75(a)(1)(ii) sets forth criteria for what must be included in a petition for an exemption from the need for 100 percent identity testing of dietary ingredients. Specifically, the petition must set forth the scientific rationale, and must be accompanied by scientific data and information, for the proposed alternative testing that will demonstrate that there is no material diminution of assurance, compared to the assurance provided by 100 percent identity testing, of the identity of the dietary ingredient before use when the dietary ingredient is obtained from one or more suppliers identified in the petition.[2]

If the petition is granted, then the manufacturer of the dietary supplement would not have to complete 100 percent identity testing on that particular dietary ingredient when it is received from the supplier specified in the petition.[3] Instead, the manufacturer would have to conduct the tests and examinations for the dietary ingredient under the terms specified by FDA when the petition is granted. Such alternative testing would be based on a scientific method (as explained in the manufacturer's petition to FDA) to establish that there is no material diminution of assurance of the identity of the ingredients, compared to the assurance provided by 100 percent identity testing. For example, the level of continued testing at a rate less than 100 percent should provide the statistical confidence that the probability of receiving a dietary ingredient that does not meet the established specifications for identity is less than a small chosen percentage at a statistical confidence level, e.g., 95 percent.

The exemption from 100 percent identity testing of dietary ingredients gives dietary supplement manufacturers, who choose to request an alternative testing regime and obtain permission from FDA for an exemption, potential relief from the burden of having to test the identity of every lot of dietary ingredients, while not reducing the quality of such ingredients used in the manufacture of finished products.

2. IFR Coverage

Number of establishments affected

In the regulatory impact analysis of the CGMP final rule, published elsewhere in this issue of the **Federal Register**, FDA identifies 1,460 establishments that manufacture, pack, hold, label, or otherwise process dietary supplements. The CGMP final rule requires 100 percent identity testing of all dietary ingredients used in the manufacture of dietary supplements. Firms who take advantage of the exemption petition process in this IFR would not have to complete 100 percent identity testing after a sufficient period of time[4] in which 100 percent identity testing has been done by the firm and data has been collected to support its alternative testing regime.

We do not know how many firms will take advantage of the option to petition FDA. For purposes of this analysis we present two petition application rate scenarios in our following estimates; a slower rate and a faster rate of application. The slower rate assumes that 10 percent of firms will petition FDA in the first year and an additional 20 percent of firms will petition FDA in years 2 through 4. A steady state is assumed for year 5 and beyond where 30 percent of firms will still be conducting 100 percent identity testing, 60 percent of firms will be conducting verification testing only and 10 percent of firms will be petitioning FDA. The faster petition submission rate scenario assumes 50 percent of firms will petition FDA in the first year, 20 percent of firms will petition in year 2, and 10 percent of firms will petition in each of years 3 and 4. The steady state rate for year 5 and beyond assumes that 10 percent of firms will still be conducting 100 percent identity testing, 80 percent of firms will be conducting verification testing only, and 10 percent of firms will be petitioning FDA.

3. Costs and Benefits of Exemption Provision

The baseline for this analysis is the costs and benefits of the CGMP final rule, published elsewhere in this issue of the **Federal Register**. We will discuss the changes from the baseline (the changes in costs and benefits from the final rule), as the result of the petition process and possible outcomes, in this IFR analysis.

In order to achieve a level of assurance for incoming ingredients that will demonstrate that there is no material diminution of assurance, compared to the assurance provided by 100 percent identity testing, firms would have to use models that incorporate representative sampling, to ensure that the incoming materials they receive are what they are intended to be. We will assume that firms may, through a combination of supplier risk evaluations and 100 percent sampling followed by verification testing, achieve a level of assurance that continued 100 percent testing would generate. The level of continued testing at a rate less than 100 percent should provide the statistical confidence that the probability of receiving a dietary ingredient that does not meet the established specifications for identity is less than a small chosen percentage at a statistical confidence level, e.g., 95 percent. Although FDA is not prescribing exactly what each manufacturer would do to establish this assurance, we will present a likely mechanism as a means of estimating the cost savings (from 100 percent testing) of this approach.

In any given year, a firm may be in one of three states with respect to incoming ingredients:

- State 1 consists of 100 percent testing of all incoming ingredients (default-baseline).
- State 2 consists of:

1. 100 percent sampling over a period of time (such as a year) with no tests indicating that the ingredient purporting to be the dietary ingredient was not the dietary ingredient;

2. Completed risk evaluations of the ingredient supplier (performed by the manufacturer or third party auditors) finding a low risk of shipping the wrong ingredient (as well as assuring that the supplier firm had a comprehensive quality control system described later in this analysis); and,

3. A scientific showing that the information from the two prior results

[2] The identity of the dietary ingredient may include more than one attribute (see discussion in section X.G.2 of the CGMP final rule). For example, identity may include physical characteristics (such as crystal or powder), state of hydration, or part of the plant (roots or leaves). The term ''identity'' would include the manufacturer's specification(s) that would identify the attributes a supplier must meet.

[3] Multiple dietary ingredients and suppliers can be discussed in the petition as long as testing on each ingredient and information about each supplier is fully documented.

[4] What a ''sufficient period of time'' is would likely vary, depending, for example, on the supplier, the identity specifications, controls that are in place to ensure that a consistent product is produced, and the risk of false identity of the dietary ingredient. Therefore, the provision does not specify how long testing would need to be done before a petition would be appropriate. For purposes of this analysis, we assume that the timeframe would be 1 year.

would allow a reduced rate of testing that would result in no material diminution of assurance in the identity of the dietary ingredient as compared to continued 100 percent testing. This data will be contained in a petition to the agency as support for the recommended representative testing scheme.

If FDA grants the petition, firms will be required to do verification testing, instead of ongoing 100 percent identity testing, and to keep records of such testing.[5] State 2 is presumed to exist any time there is a new supplier, new ingredients, new specification(s), or a new dietary supplement manufacturer who receives incoming dietary ingredients.

- State 3 consists of verification testing only.

Assumptions and costs associated with this IFR

We assume that some manufacturers will complete the 100 percent identity testing of dietary ingredients and supplier risk evaluations to provide data to support a petition request to the agency. The cost savings associated with the petition exemption process would come from those manufacturers who complete 100 percent identity testing of dietary ingredients for a period of time, obtain data that can be used as part of a qualitative evaluation of risk associated with a particular dietary ingredient/supplier combination, develop a verification testing process, and then petition the agency for the identity testing exemption. For purposes of this analysis, we expect the petition to include information about the supplier(s), the dietary ingredient(s) and its identity specification(s), information about the manufacturer and its testing, and the test results from the supplier and manufacturer for the dietary ingredient(s). We expect that the manufacturer will provide data to support a system to assure no material diminution of assurance as 100 percent identity testing, e.g., the level of continued testing at a rate less than 100 percent should provide the statistical confidence that the probability of receiving a dietary ingredient that does not meet the established specifications for identity is less than a small chosen percentage at a statistical confidence level.

We also assume that firm size, resources available, and number of incoming ingredient lots received annually will likely play a large role in which firms apply for an exemption from 100 percent testing. Firms that do not receive many ingredient lots annually will probably not find it cost effective to apply for an exemption because the costs of developing a verification testing method and conducting third party audits would reduce or eliminate any cost savings from reduced identity testing.

For those firms that do see an incentive to petition for an exemption, we assume that some proportion of them will be able to develop the information described previously in bullets 1 and 2 under State 2. We also assume that, for some firms, this information provides adequate support to allow them to implement a verification testing scheme with a the level of continued testing at a rate less than 100 percent that should provide the statistical confidence that the probability of receiving a dietary ingredient that does not meet the established specifications for identity is less than a small chosen percentage at a statistical confidence level, e.g., 95 percent. Table 1 of this document shows a verification testing scheme for identity verification testing that is equal to the square root (SQRT) of (n) +1.[6] We request comment on the use of this sampling plan for this purpose. Under this verification testing scheme, the cost savings of applying for an exemption increases as the number of lots increase above 100 lots per year. Thus, applying for an exemption is more cost effective for firms that receive 100 lots or greater for a particular ingredient per year.

TABLE 1.—TESTING RATES AT SQRT (n) + 1

Number of Lots per Year						
Total	10	50	100	1,000	5,000	10,000
Sampled	4	8	11	32	72	101
Percent sampled	40%	16%	10%	3.0%	1.4%	1.0%

If, for example, the petitioner chooses to follow FDA Office of Regulatory Affairs' inspection guidelines that direct the conduct of field investigational activities, including those related to the assessment of violations under the adulteration provisions of the act,[7] the petitioner would propose setting an upper and lower limit for verification testing of incoming ingredient lots. For example, plausible limits would be a minimum of 11 lots for manufacturers with incoming lots of 100 or less per ingredient (about 10 percent of lots), all lots if the total was less than 10 annually (these manufacturers would not apply for an exemption as they would still be testing 100 percent with or without the exemption) and a maximum of 32 lots for all manufacturers that have 1,000 or more incoming lots per ingredient tested annually. We use these verification testing limits when we estimate the cost savings that follow.

Costs to firms who petition for exemption

As stated previously, firms that intend to petition for an exemption from 100 percent identity testing will incur costs which, at a minimum will include: Employing a statistical expert to develop a verification testing plan that can prove the firm can adhere to the standard of ''no material diminution of assurance''; performing in-house, or contracting out for, a risk evaluation for each ingredient and supplier; and, providing the results of some period of 100 percent testing (which we assume

[5] The records of the verification testing would be subsumed under subpart J, § 111.325 of the CGMP final rule published elsewhere in this issue of the **Federal Register**.

[6] While statistical sampling plans are numerous, we chose the SQRT of (n) +1 from a normal distribution for ease of use. The above sampling chart (of SQRT of (n) + 1 values) assumes normal Gaussian distribution of error and loses accuracy in the lower ends of the distribution. This method of sampling was not specifically designed for confirming identity. FDA's Office of Regulatory Affairs, Investigations Operation Manual (IOM) uses the SQRT of (n) + 1 rule for compliance sampling, including chemical contamination, filth, pesticides, mold, bacteria, and identity.

[7] See FDA Investigations Operations Manual 2006, sec 4.3.7.2 on *Random Sampling*.

for purposes of this analysis to be 1 year).

In addition, as part of the supplier risk evaluation, we assume suppliers would demonstrate to manufacturers that they have a quality management system (QMS) in place and that it has been independently audited (certified) by a third party. We assume this QMS would, at a minimum, contain the following procedures:

1. Monitoring of manufacturing processes to ensure they are producing quality product;
2. Keeping proper records;
3. Checking outgoing product for defects, with appropriate corrective action where necessary; and,
4. Regularly reviewing individual processes and the quality system itself for effectiveness.

100 percent identity testing

The costs for 100 percent identity testing are calculated using the Identity Testing Model from the CGMP final rule published elsewhere in this issue of the **Federal Register**. The costs of 100 percent identity testing are costs of the final rule, not this IFR.

Statistical sampling plan for verification testing

Developing a statistical sampling plan that will assure a firm of adhering to the standard of ''no material diminution of assurance'' may vary with firm size, supplier or manufacturer characteristics, nature of the dietary ingredient, or type of dietary supplement manufactured. Thus, firms wishing to get an exemption from 100 percent identity testing may hire a statistician to develop a verification testing plan that will be acceptable to FDA. Using a statistician's mean hourly wage of $31.79, (Ref. 1), plus 50 percent for overhead, we estimate it will take a statistician 20 hours to develop an appropriate plan. The total cost for a statistician would be $954 ($47.69 per hour X 20 hours). We request comment on this estimate.

Supplier risk evaluations (Third party audits)

We assume that qualitative supplier risk evaluations would be developed and then administered to a firm's suppliers. We expect manufacturing firms would hire a risk analyst to develop an appropriate supplier risk evaluation, administer it to the suppliers in question, and then analyze the results. We estimate that it will take a risk analyst 40 hours to conduct the work necessary to have complete evaluations of ingredient suppliers' risk.[8] We use the hourly mean wage of a risk management analyst ($27.90) (Ref. 1), plus 50 percent for overhead to calculate the cost of completing the supplier risk evaluations. The total cost for supplier risk evaluations is $1,674 ($41.85 per hour x 40 hours). We request comment on this estimate.

As stated previously, since FDA is not prescribing a specific scientific method for how dietary supplement manufacturers can assure the identity of a dietary ingredient when less than 100 percent identity testing is performed, there may be many ways that dietary supplement manufacturers may conduct risk evaluations or develop a verification testing plan as part of the petition process.

One possible scenario is that market forces could cause a new industry to evolve whereby a third party or an intermediary conduct identity tests on dietary ingredients and/or perform supplier risk evaluations and sell the results. Certain suppliers of dietary ingredients may find it to their competitive advantage to hire an independent third party to conduct such testing. These intermediaries might obtain samples from a variety of suppliers over the course of a year, test those samples for identity using certain specifications, and then sell the results of the year's testing to dietary supplement manufacturers—e.g., small businesses who cannot test on their own and would have to contract out the testing. Another possibility is that manufacturers sell the results of testing and risk evaluation to other manufacturers or the original supplier. The supplier may use such information in marketing as an incentive for manufacturers to buy that supplier's product.

Petition process

The petitions, which we assume would include the results of 1 year's testing (for purposes of this analysis), the recommended verification testing plan, and the supplier risk evaluation, will sort those manufacturers who have reliable suppliers from those that do not. The petition is assumed to take 8 hours per plant for assembly of the information.[9] The wage for a first-line production supervisor ($23.66) (Ref. 1), plus 50 percent for overhead, is used to estimate the costs of petition assembly. The total cost of assembling a single petition, for single or multiple ingredients and suppliers, is estimated to be about $284 (8 hours x $35.49 per hour).

Costs of quality management systems and certification

For those suppliers who do not have QMS, the costs of putting them into place are likely to run into tens of thousands of dollars. A supplier would only install this type of system if they wish to sell, or continue selling, to manufacturers who are likely to petition the agency for an exemption from 100 percent testing. As presently constructed, it is likely that only larger firms who are more able to bear the fixed costs of the rule (supplier risk evaluations, certification costs, and costs of preparing petitions) are likely to petition the agency for an exemption. Further, we assume that virtually all suppliers to these large manufacturers already have some sort of a QMS in place, particularly those that are domestic. However, it is unclear how many foreign suppliers have these systems. FDA has no data on the number of supplier firms who might have such systems and is unable to estimate the likely cost additions of either putting these systems in or the cost of certifying these systems. Therefore, all cost estimates contained in this analysis should be viewed as lower bounds.

Total costs to firms

Table 2 shows the total costs per firm to submit a petition for an exemption from 100 percent identity testing of dietary ingredients used in the manufacture of dietary supplements.

TABLE 2.—TOTAL COSTS PER FIRM TO SUBMIT A PETITION FOR EXEMPTION FROM 100 PERCENT IDENTITY TESTING

Activity	Cost
Verification Testing Plan	$954
Risk Evaluation	$1,674
Petition Assembly	$284
Total Cost Per Firm	$2,912

Petition review

It will take FDA approximately 40 hours to review a petition. The cost of each petition review would be $1,826 (40 hours x $45.65 per hour).[10]

Amendments and updates to petitions

In cases where a petition has been granted and the manufacturer has changed ingredients, specifications, or suppliers or any combination thereof,

[8] This is an average cost. The time needed and therefore the cost of evaluations may be more or less depending on the number of suppliers and ingredients that are being evaluated.

[9] In the analysis of the final rule we determined that vitamin and mineral products contain about 13 listed dietary ingredients per product and other dietary supplements, mainly herbals, contain about 4 listed dietary ingredients per product.

[10] Pay for an employee earning a GS-13, step 7 adjusted to include locality pay for Washington, DC and the surrounding area.

we assume that the original petition would no longer be applicable and a new petition would need to be submitted. We do not attempt to calculate the costs of amendments and updates to petitions here. However, we note that manufacturers are likely to take the likelihood of these changes into account before beginning the process of gathering information to submit a petition. The sooner the likelihood of a change, the less likely a manufacturer will petition for an exemption.

If at any time verification testing conducted by the manufacturer produces an ingredient that is not the correct ingredient, the approved petition would no longer be considered in effect, and the manufacturer would need to return to 100 percent identity testing and re-petition for another exemption.

Petition approval uncertainty

We assume that not all firms that petition FDA will be approved for an exemption from 100 percent identity testing (for example, some petitions may contain insufficient data or an unacceptable verification testing plan). Another reason for the uncertainty in application and acceptance rates is the degree of uncertainty manufacturers face about acceptance of their plan. However, at some point, FDA may have sufficient data to provide more information about classes of dietary ingredients and supplier conditions so as to be able to provide manufacturers with more standardized information that will help them choose a plan. Some degree of uncertainty also exists for small firms as, given the verification testing plan outlined previously, firms receiving fewer than 10 incoming lots of a specific ingredient annually will not benefit from a petition exemption (all lots would still have to be tested).

We cannot know what percentage of firms will apply for exemption or what percentage of firms will be successful in their petition submission. Table 3 diagrams how firms may respond to the option of petitioning FDA for exemption based on firm size.

TABLE 3.—LIKELIHOOD OF PETITION ATTEMPTS BY FIRM SIZE

Firm Size	Likelihood of Petition Submission		
	Do not Petition	Petition	Petition Success
Very Small (< 20 employees)	Most	Few	?
Small (20 to 499 employees)	Some	Some	?
Large (500 or more employees)	Few	Most	?

Estimated cost savings from petition exemptions

The cost savings associated with the testing exemption provided for in this IFR are highly dependent on:

- The number of tests required for verification that is allowed in the place of on-going 100 percent identity testing,
- How many firms apply for exemption,
- How many ingredients firms apply for exemption from testing for, and,
- The likelihood that FDA will approve the exemption.

Nevertheless, we assume that it is likely that firms will assume their petition exemption will be successful if they provide the required documentation and assert that they will follow a verification sampling plan based on the bounded square root of (n)+1 methodology outlined previously.

Expected cost savings from petition exemptions: $7.3 to $37.3 million per year

Years 1 through 5 cost estimates for 100 percent testing and for verification testing are shown in table 4 of this document. The cost savings associated with this IFR are calculated by subtracting the cost estimates for year 5, respectively, from the estimated cost for 100 percent testing. Steady state costs are calculated, where the fixed costs of the risk evaluation and petition process are amortized over a 10-year period.[11]

Table 4 presents the cost savings as they would be realized under two petition application rate scenarios; a slower rate and a faster rate of application. The slower rate assumes that about 10 percent of firms will petition FDA in the first year and an additional 20 percent of firms will petition FDA in years 2 through 4. A steady state is assumed for year 5 and beyond where 30 percent of firms will still be conducting 100 percent identity testing, 60 percent of firms will be conducting verification testing only and 10 percent of firms will be petitioning FDA. The faster petition submission rate scenario assumes about 50 percent of firms will petition FDA in the first year, 20 percent of firms will petition in year 2, and 10 percent of firms will petition in each of years 3 and 4. The steady state rate for year 5 and beyond assumes that 10 percent of firms will still be conducting 100 percent identity testing, 80 percent of firms will be conducting verification testing only, and 10 percent of firms will be petitioning FDA. Given the uncertainty of petition success, we expect the lower petition exemption submission rate by industry is more likely, and if so, would mean a lower cost savings for this IFR.

We also base the cost savings in table 4 on the probability that verification testing plans for very small and small firms will require 10 percent testing and that verification testing plans for large firms will require 3 percent testing. We base this on the assumption that very small and small firms would receive 100 lots or less annually of a particular dietary ingredient and, following the verification testing plan outlined previously, would be required to test at most 10 lots or 10 percent of all lots; large firms are assumed to receive 1,000 or more lots annually of a specific ingredient and would be required to test 30 lots at most or no more than 3 percent of all lots.

We cannot know if dietary supplement manufacturers will petition for exemptions for all dietary ingredients used in their products. In the analysis of the CGMP final rule we determined that vitamin and mineral products contain about 13 listed dietary ingredients per product and other dietary supplements, mainly herbals, contain about 4 listed dietary ingredients per product. We do not specify in our cost savings how many ingredients and suppliers are included in a manufacturer's petition. The cost estimate for risk evaluations calculated previously and used in table 4 is meant

[11] Amortization rate over 10 years for fixed costs is 7 percent. The estimates do not change when the amortization rate is 3 percent.

to take into consideration multiple ingredients and suppliers might be included in a single petition.

Several cost savings scenarios are shown in table 4 to represent uncertainty about who will petition for an exemption.

TABLE 4.—COSTS OF IDENTITY TESTING FOR 100% TESTING AND FOR VERIFICATION SAMPLING (IN MILLIONS OF DOLLARS)

Cost Estimate of 100% Identity Testing

	Year 1	Year 2	Year 3	Year 4	Year 5	Steady State After Year 5 (r = 7%)
Total Costs for 100% Identity Testing	$45.9	$45.9	$45.9	$45.9	$45.9	$45.9
Slower adoption of exemption						
Total Costs for Verification Testing	$42.4	$34.8	$26.5	$18.2	$17.5	$16.9
Cost Savings	$3.5	$11.1	$19.4	$27.7	$28.4	$29.0
Faster adoption of exemption						
Total Costs for Verification Testing	$28.6	$18.2	$13.3	$13.3	$9.2	$8.6
Cost Savings	$17.3	$27.7	$32.6	$32.6	$36.7	$37.3

Table 5 takes the estimates from table 4 and adjusts them to represent different rates of petition success.

TABLE 5. COST SAVINGS WHEN PETITION SUCCESS RATE IS NOT 100% BASED ON STEADY STATE AFTER YEAR 5 (R=7%) FROM TABLE 3 (IN MILLIONS OF DOLLARS)

	100% Exemption Success Rate	75% Exemption Success Rate	50% Exemption Success Rate	25% Exemption Success Rate
Cost Savings slower adoption rate	$29.0	$21.8	$14.5	$7.3
Cost Savings faster adoption rate	$37.3	$28.0	$18.7	$9.3

Benefits

The IFR provisions will cause no net change in the benefits from the final rule with the exception of any potential benefits from suppliers putting QMS in place. The provisions of the IFR still lead to the following benefits:

- Reduced health costs associated with a reduced number of acute illnesses;
- Fewer product recalls; and
- Reduced health costs associated with a reduced number of chronic illnesses and conditions.

The opportunity the IFR provides for reduced identity testing of dietary ingredients should not change these benefits.

If, in fact, any suppliers install QMSs as a result of this rule, the benefits would be that raw materials would be less likely to be contaminated or adulterated. So if the raw material is less likely to be contaminated or adulterated, then dietary supplements that are made with that raw material are also less likely to be contaminated and adulterated.

B. Final Regulatory Flexibility Analysis

FDA has examined the economic implications of this IFR as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. FDA has concluded that this IFR will not have a significant economic impact on a substantial number of small entities.

FDA determined in the CGMP final rule that there are 774 very small establishments (less than 20 employees) and 526 small establishments (20 to 499 employees) that will be affected by the requirements of the CGMP final rule. These establishments may or may not take advantage of the petition exemption process provided for in this IFR.

The likelihood of very small and small firms taking advantage of the exemption depends largely on the annual minimum number of lots of dietary ingredients for which they will have to test for identity and the size of the fixed costs associated with the supplier risk evaluation and petition costs. FDA has not specified how many lots are an acceptable minimum. If a plausible limit is a minimum of 10 lots for manufacturers with incoming lots of 100 or less per ingredient (about 10 percent of lots) and all lots total less than 10 annually, then there will be some small and very small manufacturers who will not apply for an exemption because they would still have to test 100 percent of incoming lots for identity whether they applied for an exemption or not.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $118 million, using the most current (2004) Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this IFR does not constitute a significant rule under the Unfunded Mandates Reform Act.

IV. Paperwork Reduction Act of 1995

This IFR contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of these provisions are shown in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the interim final collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the interim final collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

Description: Section 402(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(g)) gives us explicit authority to issue a rule establishing CGMP requirements for dietary supplements. Section 402(g)(1) of the act states that a dietary supplement is adulterated if ''it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.'' Section 402(g)(2) of the act authorizes us to, by regulation, ''prescribe good manufacturing practices for dietary supplements.'' Under section 701(a) of the act (21 U.S.C. 371), FDA may issue regulations necessary for the efficient enforcement of the act. Other relevant legal authority is discussed in section V of the CGMP final rule. In the PRA analysis of the CGMP final rule (section XXVIII), we discuss why records are an indispensable component of CGMP (and incorporate that discussion by reference in this IFR).

Under § 111.75(a)(1), the CGMP final rule requires the manufacturer of a dietary supplement to conduct at least one appropriate test or examination on every incoming lot to verify the identity of any component that is a dietary ingredient before it is used in the manufacture of a dietary supplement. This IFR modifies § 111.75(a)(1) and renumbers it as § 111.75(a)(1)(i) and adds § 111.75(a)(1)(ii). Section 111.75(a)(1)(i) requires what is in § 111.75(a)(1) of the CGMP final rule, but adds the following exception, ''unless you petition the agency under subparagraph (1)(ii) of this paragraph and the agency exempts you from such testing.'' Section 111.75(a)(1)(ii) sets forth criteria for what must be included in a petition for an exemption from the need for 100 percent identity testing of dietary ingredients. Specifically, the petition must set forth the scientific rationale, and must be accompanied by scientific data and information, for proposed alternative testing that will demonstrate that there is no material diminution of assurance, compared to the assurance provided by 100 percent identity testing, of the identity of the dietary ingredient before use when the dietary ingredient is obtained from one or more suppliers identified in the petition.

Description of Respondents: Manufacturers, dietary supplement manufacturers, packagers and re-packagers, labelers and re-labelers, holders, distributors, warehousers, exporters, importers, large businesses, and small businesses.

FDA estimates the burden for this information collection as follows:

TABLE 6.—ESTIMATED ONE-TIME BURDEN TO PETITION FDA[1]

21 CFR Section	Number of Recordkeepers	Frequency per Recordkeeping	Total Records	Hours per Record	Total Hours
111.75 (a)1(b)	1,460	1	1,460	8	11,680
111.95	1,460	1	1460	0.1	146
Total One time burden					11,826

[1] There are no capital costs or operating costs associated with the collection of information under this IFR.

One-time Burden

In the regulatory impact analysis of the CGMP final rule, published elsewhere in this issue of the **Federal Register**, FDA identifies 1,460 establishments that manufacture, pack, hold, label, or otherwise process dietary supplements. We assume that at least some manufacturers would like to take advantage of the opportunity to petition FDA to eliminate the need to do 100 percent identity testing for the dietary ingredients they use in the manufacture of their products. Therefore, for this PRA analysis, we will make an assumption that every establishment will submit a petition to FDA for review and approval requesting an exemption from 100 percent identity testing for at least one dietary ingredient from at least one supplier. We ask for comment about whether manufacturers would be interested in seeking an exemption for 100 percent identity testing, and if so, for how many ingredients and from how many suppliers.

As stated in the previous analysis, the petitions, which we assume would include the results of 1 year's testing, verification testing plan, and the supplier risk evaluation, will take 8 hours per plant for assembly of the information. Assuming that all establishments submit a petition for exemption for at least one dietary ingredient/supplier combination, the hour burden estimate for this activity is

11,680 hours (1,460 establishments x 8 hours per establishment).

Recordkeeping Burden

We assume that the only recurring burden would be only for maintenance of records. The records of the verification testing would be subsumed under § 111.325 of the final rule published elsewhere in this issue of the **Federal Register**. FDA's response to the petition submitted under § 111.75(a)(1)(ii) would be a new record associated with this IFR under § 111.95. This would be, at a minimum, a one-time burden for each establishment that petitioned the agency for an exemption. Again, assuming that each firm petitions the agency, the burden would be 146 hours (0.1 hours x 1460 firms).

The information collection provisions of this IFR have been submitted to OMB for review. Interested persons are requested to fax comments regarding the information collection by (see **DATES**), to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**).

Prior to the effective date of this IFR, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Comments

FDA is issuing this rule as an IFR, with an opportunity for public comment. Although the agency is seeking comment on this IFR, it is effective August 24, 2007.

Compliance Dates: The compliance date is June 25, 2008; except that for businesses employing fewer than 500, but 20 or more full-time equivalent employees, the compliance date is June 25, 2009; and except that for businesses that employ fewer than 20 full-time equivalent employees, the compliance date is June 25, 2010. This means that the rule's requirements will be in effect and have the force and effect of law from those dates until any subsequent modification by the issuance of a final rule.

FDA will consider all comments submitted. FDA is dedicated to updating the Regulatory Impact Analysis with the best available information in order to inform decisionmakers who may be considering regulatory alternatives in developing a final rule. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this IFR. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit one electronic copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. We will address comments received and confirm or modify the IFR in a final rule. We will not consider any comments previously considered during the rulemaking for the CGMP final rule, published elsewhere in this **Federal Register**.

VI. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. We have concluded under § 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this IFR in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' FDA has determined that the IFR does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the IFR does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ISO 9001–2005, Quality Management Systems—Fundamentals and Vocabulary.

E1. Occupational Employment and Wages, May 2005, Bureau of Labor Statistics, *www.bls.gov*, accessed March 20, 2006.

List of Subjects

21 CFR Part 111

Dietary foods, Drugs, Foods, Packaging and containers.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 111 is amended as follows:

PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

■ 1. The authority citation for 21 CFR part 111 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 371, 374, 381, 393; 42 U.S.C. 264.

■ 2. Section 111.75 is amended by revising paragraph (a)(1) to read as follows:

§ 111.75 What must you do to determine whether specifications are met?

(a) * * *

(1)(i) Conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, unless you petition the agency under paragraph (a)(1)(ii) of this section and the agency exempts you from such testing;

(ii) You may submit a petition, under 21 CFR 10.30, to request an exemption from the testing requirements in paragraph (a)(1)(i) of this section. The petition must set forth the scientific rationale, and must be accompanied by the supporting data and information, for proposed alternative testing that will demonstrate that there is no material diminution of assurance, compared to the assurance provided by 100 percent identity testing, of the identity of the dietary ingredient before use when the dietary ingredient is obtained from one or more suppliers identified in the petition. If FDA grants the petition, you must conduct the tests and examinations for the dietary ingredient, otherwise required under § 111.75(a)(1)(i), under the terms specified by FDA when the petition is granted; and

* * * * *

■ 3. Section 111.95 is amended by adding new paragraph (b)(6) to read as follows:

§ 111.95 Under this subpart E, what records must you make and keep?

* * * * *

(b) * * *

(6) Documentation of FDA's response to a petition submitted under § 111.75(a)(1)(ii) providing for an exemption from the provisions of § 111.75(a)(1)(i).

Dated: May 8, 2007.

Andrew C. von Eschenbach,

Commissioner of Food and Drugs.

Dated: May 8, 2007.

Michael O. Leavitt,

Secretary of Health and Human Services.

[FR Doc. 07–3038 Filed 6–22–07; 8:45 am]

BILLING CODE 4160–01–S

Federal Register

Monday,
June 25, 2007

Part III

The President

Federal Register
Vol. 72, No. 121
Monday, June 25, 2007

Presidential Documents

Title 3—

The President

Presidential Determination No. 2007–20 of June 1, 2007

Assistance for the West Bank and Gaza

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 550(b) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 2006 (FOAA)(Public Law 109–102), as amended by the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006 (Public Law 109–234), sections 620K(e) and 620L(b)(4) of the Foreign Assistance Act, as added by the Palestinian Anti-Terrorism Act of 2006 (Public Law 109–446), and section 301 of title 3, United States Code, I hereby certify and report that:

With respect to the provision of assistance for the administrative and personal security costs of the Office of the President of the Palestinian Authority; for the activities of the President of the Palestinian Authority to promote democracy, peaceful resolution of the Israeli-Palestinian conflict, and the rule of law and to fulfill his duties as President, including, among other things, to maintain control of the management and security of border crossings and to foster the Middle East peace process; and, with respect to independent agencies:

- it is in the national security interest of the United States to provide such assistance;
- as the case may be, the President of the Palestinian Authority, the President's party, and independent agencies and any members thereof, including any individual or entity for which assistance is proposed to be provided, are not members of, appointed by, or effectively controlled by Hamas or any other foreign terrorist organization; and
- such assistance provided hereunder will not be transferred or retransferred to any member of Hamas or other foreign terrorist organization or to any entity effectively controlled by Hamas or other foreign terrorist organization.

Accordingly, I hereby waive section 550(a) of the FOAA, as amended, and section 620K(a) of the Foreign Assistance Act, as amended, with respect to such assistance, and authorize such assistance for the above purposes.

Furthermore, I hereby determine that, with respect to assistance to nongovernmental organizations for the West Bank and Gaza other than assistance covered by paragraphs (b)(1), (2), and (3) of section 620L of the Foreign Assistance Act, as amended, it is in the national security interest of the United States to provide such assistance as the Secretary of State deems appropriate, and assign to the Secretary of State the functions under section 620L(b)(4)(B) regarding the specific programs, projects, and activities to be carried out using such assistance.

I also hereby assign the functions of the President under section 550(b) and (c) of the FOAA, as amended and as carried forward under the Revised Continuing Appropriations Resolution, 2007 (Public Law 110–5), to the Secretary of State.

You are hereby authorized and directed to report this determination to the Congress and publish it in the **Federal Register**.

THE WHITE HOUSE,
Washington, June 1, 2007.

[FR Doc. 07–3137
Filed 6–22–07; 9:57 am]
Billing code 4710–10

Presidential Documents

Presidential Determination No. 2007–21 of June 1, 2007

Suspension of Limitations Under the Jerusalem Embassy Act

Memorandum for the Secretary of State

Pursuant to the authority vested in me as President by the Constitution and the laws of the United States, including section 7(a) of the Jerusalem Embassy Act of 1995 (Public Law 104–45) (the ''Act''), I hereby determine that it is necessary to protect the national security interests of the United States to suspend for a period of 6 months the limitations set forth in sections 3(b) and 7(b) of the Act. My Administration remains committed to beginning the process of moving our Embassy to Jerusalem.

You are hereby authorized and directed to transmit this determination to the Congress, accompanied by a report in accordance with section 7(a) of the Act, and to publish the determination in the **Federal Register**.

This suspension shall take effect after transmission of this determination and report to the Congress.

THE WHITE HOUSE,
Washington, June 1, 2007.

[FR Doc. 07–3138
Filed 6–22–07; 9:57 am]
Billing code 4710–10

Presidential Documents

Memorandum of June 12, 2007

Assignment of Certain Reporting Functions of the John Warner National Defense Authorization Act for Fiscal Year 2007

Memorandum for the Secretary of State[,] Secretary of Defense[, and the] Director of National Intelligence

By virtue of the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, I hereby assign to the Secretary of State the functions of the President under sections 1211(b), 1213(b), and 1226(c) of the John Warner National Defense Authorization Act for Fiscal Year 2007 (Public Law 109–364).

In the performance of such functions, the Secretary of State should coordinate with the Secretary of Defense and the Director of National Intelligence, and the heads of other departments and agencies, as appropriate.

The Secretary of State is authorized and directed to publish this memorandum in the **Federal Register**.

THE WHITE HOUSE,
Washington, June 12, 2007.

[FR Doc. 07–3139
Filed 6–22–07; 9:57 am]
Billing code 4710–10

Federal Register

Monday,
June 25, 2007

Part IV

The President

Notice of June 22, 2007—Continuation of the National Emergency With Respect to the Western Balkans

Federal Register
Vol. 72, No. 121
Monday, June 25, 2007

Presidential Documents

Title 3—

The President

Notice of June 22, 2007

Continuation of the National Emergency With Respect to the Western Balkans

On June 26, 2001, by Executive Order 13219, I declared a national emergency with respect to the Western Balkans pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of persons engaged in, or assisting, sponsoring, or supporting (i) extremist violence in the Republic of Macedonia and elsewhere in the Western Balkans region, or (ii) acts obstructing implementation of the Dayton Accords in Bosnia or United Nations Security Council Resolution 1244 of June 10, 1999, in Kosovo. I subsequently amended that order in Executive Order 13304 of May 28, 2003.

Because the actions of persons threatening the peace and international stabilization efforts in the Western Balkans continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States, the national emergency declared on June 26, 2001, and the measures adopted on that date and thereafter to deal with that emergency, must continue in effect beyond June 26, 2007. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to the Western Balkans.

This notice shall be published in the **Federal Register** and transmitted to the Congress.

THE WHITE HOUSE,
June 22, 2007.

[FR Doc. 07–3143
Filed 6–22–07; 10:40 am]
Billing code 3195–01–P

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Federal Register

Vol. 72, No. 121

Monday, June 25, 2007

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CFR PARTS AFFECTED DURING JUNE

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT JUNE 25, 2007

DEFENSE DEPARTMENT

Army Department

Law enforcement and criminal investigations:

Law enforcement reporting; policies and procedures; published 5-24-07

ENERGY DEPARTMENT

Acquisition regulations:

Management and operating contracts; cooperative audit strategy; implementation; published 5-24-07

ENERGY DEPARTMENT

Federal Energy Regulatory Commission

Public Utility Regulatory Policies Act:

Small power production and cogeneration facilities; published 5-24-07

ENVIRONMENTAL PROTECTION AGENCY

Air pollutants, hazardous; national emission standards:

Surface coating of automobiles, light-duty trucks, and plastic parts and products; published 4-24-07

Air pollution control:

State operating permits programs—

Maryland; published 4-25-07

Air pollution control; recreational engines and vehicles:

All terrain vehicles; temporary exhaust emission test procedure option; extension; published 4-26-07

FEDERAL COMMUNICATIONS COMMISSION

Radio stations; table of assignments:

West Virginia; published 5-30-07

HOMELAND SECURITY DEPARTMENT

Coast Guard

Drawbridge operations:

New York; published 6-11-07

Ports and waterways safety; regulated navigation areas, safety zones, security zones, etc.:

Mystic Seaport and Mystic River, CT; published 6-20-07

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Foreign corporations; gross income exclusions; published 6-25-07

VETERANS AFFAIRS DEPARTMENT

Vocational rehabilitation and education:

Veterans education—

Educational institutions with multi-state campuses; centralized certifications of enrollment; published 4-25-07

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Agricultural Marketing Service

Cherries (sweet) grown in Washington; comments due by 7-2-07; published 6-20-07 [FR E7-11820]

Nectarines and peaches grown in California; comments due by 7-2-07; published 6-20-07 [FR E7-11822]

Onions grown in South Texas; comments due by 7-6-07; published 5-7-07 [FR E7-08626]

AGRICULTURE DEPARTMENT

Grain Inspection, Packers and Stockyards Administration

Grade standards:

Soybeans; comments due by 7-2-07; published 5-1-07 [FR E7-08291]

DEFENSE DEPARTMENT

Federal Acquisition Regulation (FAR):

Construction and service contracts; use of products containing recovered materials; comments due by 7-2-07; published 5-3-07 [FR 07-02168]

Military recruiting and Reserve Officer Training Corps program access to institutions of higher learning; comments due by 7-6-07; published 5-7-07 [FR E7-08662]

ENERGY DEPARTMENT

Loan guarantees for projects that employ innovative technologies; comments due by 7-2-07; published 5-16-07 [FR E7-09297]

ENVIRONMENTAL PROTECTION AGENCY

Air pollutants, hazardous; national emission standards:

Locomotives engines and marine compression-ignition engines less than 30 liters per cylinder; comments due by 7-2-07; published 4-3-07 [FR 07-01107]

Air programs:

Outer Continental Shelf regulations—

California; consistency update; comments due by 7-2-07; published 5-31-07 [FR E7-10457]

Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:

Indiana; comments due by 7-2-07; published 5-31-07 [FR E7-09825]

Air quality implementation plans; approval and promulgation; various States:

Iowa; comments due by 7-2-07; published 5-31-07 [FR E7-10490]

Missouri; comments due by 7-2-07; published 5-31-07 [FR E7-10231]

Air quality implementation plans; approval and promulgation; various States; air quality planning purposes; designation of areas:

Pennsylvania; comments due by 7-2-07; published 6-1-07 [FR E7-10584]

Hazardous waste program authorizations:

Ohio; comments due by 7-6-07; published 6-6-07 [FR E7-10856]

Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:

Chloroneb, etc.; comments due by 7-2-07; published 5-2-07 [FR E7-08373]

Food packaging treated with pesticides; comments due by 7-6-07; published 6-6-07 [FR E7-10693]

Glyphosate; comments due by 7-2-07; published 5-2-07 [FR E7-08000]

Toxic substances:

Lead; renovation, repair, and painting program; hazard exposure reduction; comments due by 7-5-07; published 6-5-07 [FR E7-10797]

Water programs:

Drinking water contaminant candidate lists; primary contaminants; regulatory determinations; comments due by 7-2-07; published 5-1-07 [FR E7-07539]

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:

Wireless E911 location accuracy and E911 IP-enabled service providers requirements; comments due by 7-5-07; published 6-20-07 [FR E7-11404]

GENERAL SERVICES ADMINISTRATION

Federal Acquisition Regulation (FAR):

Construction and service contracts; use of products containing recovered materials; comments due by 7-2-07; published 5-3-07 [FR 07-02168]

HEALTH AND HUMAN SERVICES DEPARTMENT

Centers for Medicare & Medicaid Services

Medicare:

Hospice wage index for fiscal year 2008; comments due by 7-2-07; published 5-1-07 [FR 07-02120]

Inpatient rehabilitation facility prospective payment system (2008 FY); update; comments due by 7-2-07; published 5-8-07 [FR 07-02241]

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Food for human consumption:

Food labeling—

Irradiation in the production, processing and handling of food; comments due by 7-3-07; published 4-4-07 [FR 07-01636]

HOMELAND SECURITY DEPARTMENT

Coast Guard

Ports and waterways safety; regulated navigation areas, safety zones, security zones, etc.:

Detroit River, Detroit, MI; comments due by 7-2-07; published 6-15-07 [FR E7-11535]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

S. 676/P.L. 110–38

To provide that the Executive Director of the Inter-American Development Bank or the Alternate Executive Director of the Inter-American Development Bank may serve on the Board of Directors of the Inter-American Foundation. (June 21, 2007; 121 Stat. 230)

S. 1537/P.L. 110–39

To authorize the transfer of certain funds from the Senate Gift Shop Revolving Fund to the Senate Employee Child Care Center. (June 21, 2007; 121 Stat. 231)

Last List June 21, 2007

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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Title	Stock Number	Price	Revision Date
1	(869–062–00001–4)	5.00	[4] Jan. 1, 2007
2	(869–062–00002–2)	5.00	Jan. 1, 2007
3 (2006 Compilation and Parts 100 and 102)	(869–062–00003–1)	35.00	[1] Jan. 1, 2007
4	(869–062–00004–9)	10.00	[5] Jan. 1, 2007
5 Parts:			
1–699	(869–062–00005–7)	60.00	Jan. 1, 2007
700–1199	(869–062–00006–5)	50.00	Jan. 1, 2007
1200–End	(869–062–00007–3)	61.00	Jan. 1, 2007
6	(869–062–00008–1)	10.50	Jan. 1, 2007
7 Parts:			
1–26	(869–062–00009–0)	44.00	Jan. 1, 2007
27–52	(869–062–00010–3)	49.00	Jan. 1, 2007
53–209	(869–062–00011–1)	37.00	Jan. 1, 2007
210–299	(869–062–00012–0)	62.00	Jan. 1, 2007
300–399	(869–062–00013–8)	46.00	Jan. 1, 2007
400–699	(869–062–00014–6)	42.00	Jan. 1, 2007
700–899	(869–062–00015–4)	43.00	Jan. 1, 2007
900–999	(869–062–00016–2)	60.00	Jan. 1, 2007
1000–1199	(869–062–00017–1)	22.00	Jan. 1, 2007
1200–1599	(869–062–00018–9)	61.00	Jan. 1, 2007
1600–1899	(869–062–00019–7)	64.00	Jan. 1, 2007
1900–1939	(869–062–00020–1)	31.00	Jan. 1, 2007
1940–1949	(869–062–00021–9)	50.00	[5] Jan. 1, 2007
1950–1999	(869–062–00022–7)	46.00	Jan. 1, 2007
2000–End	(869–062–00023–5)	50.00	Jan. 1, 2007
8	(869–062–00024–3)	63.00	Jan. 1, 2007
9 Parts:			
1–199	(869–062–00025–1)	61.00	Jan. 1, 2007
200–End	(869–062–00026–0)	58.00	Jan. 1, 2007
10 Parts:			
1–50	(869–062–00027–8)	61.00	Jan. 1, 2007
51–199	(869–062–00028–6)	58.00	Jan. 1, 2007
200–499	(869–062–00029–4)	46.00	Jan. 1, 2007
500–End	(869–066–00030–8)	62.00	Jan. 1, 2007
11	(869–062–00031–6)	41.00	Jan. 1, 2007
12 Parts:			
1–199	(869–062–00032–4)	34.00	Jan. 1, 2007
200–219	(869–062–00033–2)	37.00	Jan. 1, 2007
220–299	(869–062–00034–1)	61.00	Jan. 1, 2007
300–499	(869–062–00035–9)	47.00	Jan. 1, 2007
500–599	(869–062–00036–7)	39.00	Jan. 1, 2007
600–899	(869–062–00037–5)	56.00	Jan. 1, 2007
900–End	(869–062–00038–3)	50.00	Jan. 1, 2007
13	(869–062–00039–1)	55.00	Jan. 1, 2007
14 Parts:			
1–59	(869–062–00040–5)	63.00	Jan. 1, 2007
60–139	(869–062–00041–3)	61.00	Jan. 1, 2007
140–199	(869–062–00042–1)	30.00	Jan. 1, 2007
200–1199	(869–062–00043–0)	50.00	Jan. 1, 2007
1200–End	(869–062–00044–8)	45.00	Jan. 1, 2007
15 Parts:			
0–299	(869–062–00045–6)	40.00	Jan. 1, 2007
300–799	(869–062–00046–4)	60.00	Jan. 1, 2007
800–End	(869–062–00047–2)	42.00	Jan. 1, 2007
16 Parts:			
0–999	(869–062–00048–1)	50.00	Jan. 1, 2007
1000–End	(869–062–00049–9)	60.00	Jan. 1, 2007
17 Parts:			
1–199	(869–062–00051–1)	50.00	Apr. 1, 2007
200–239	(869–060–00052–6)	60.00	Apr. 1, 2006
240–End	(869–060–00053–4)	62.00	Apr. 1, 2006
18 Parts:			
1–399	(869–060–00054–2)	62.00	Apr. 1, 2006
400–End	(869–062–00055–3)	26.00	Apr. 1, 2007
19 Parts:			
1–140	(869–060–00056–9)	61.00	Apr. 1, 2006
*141–199	(869–062–00057–0)	58.00	Apr. 1, 2007
200–End	(869–062–00058–8)	31.00	Apr. 1, 2007
20 Parts:			
1–399	(869–060–00059–3)	50.00	Apr. 1, 2006
400–499	(869–060–00060–7)	64.00	Apr. 1, 2006
500–End	(869–060–00061–5)	63.00	Apr. 1, 2006
21 Parts:			
1–99	(869–062–00062–6)	40.00	Apr. 1, 2007
100–169	(869–060–00063–1)	49.00	Apr. 1, 2006
170–199	(869–062–00064–2)	50.00	Apr. 1, 2007
200–299	(869–062–00065–1)	17.00	Apr. 1, 2007
300–499	(869–062–00066–9)	30.00	Apr. 1, 2007
500–599	(869–060–00067–4)	47.00	Apr. 1, 2006
600–799	(869–062–00068–5)	17.00	Apr. 1, 2007
800–1299	(869–060–00069–1)	60.00	Apr. 1, 2006
*1300–End	(869–062–00070–7)	25.00	Apr. 1, 2007
22 Parts:			
1–299	(869–060–00071–2)	63.00	Apr. 1, 2006
300–End	(869–060–00072–1)	45.00	[7] Apr. 1, 2006
23	(869–062–00073–7)	45.00	Apr. 1, 2007
24 Parts:			
*0–199	(869–062–00074–0)	60.00	Apr. 1, 2007
200–499	(869–060–00075–5)	50.00	Apr. 1, 2006
500–699	(869–060–00076–3)	30.00	Apr. 1, 2006
700–1699	(869–060–00077–1)	61.00	Apr. 1, 2006
1700–End	(869–062–00078–2)	30.00	Apr. 1, 2007
25	(869–060–00079–8)	64.00	Apr. 1, 2006
26 Parts:			
§§ 1.0–1–1.60	(869–062–00080–4)	49.00	Apr. 1, 2007
§§ 1.61–1.169	(869–060–00081–0)	63.00	Apr. 1, 2006
§§ 1.170–1.300	(869–060–00082–8)	60.00	Apr. 1, 2006
*§§ 1.301–1.400	(869–062–00083–9)	47.00	Apr. 1, 2007
§§ 1.401–1.440	(869–062–00084–7)	56.00	Apr. 1, 2007
*§§ 1.441–1.500	(869–062–00085–5)	58.00	Apr. 1, 2007
§§ 1.501–1.640	(869–062–00086–3)	49.00	Apr. 1, 2007
*§§ 1.641–1.850	(869–062–00087–1)	61.00	Apr. 1, 2007
§§ 1.851–1.907	(869–062–00088–0)	61.00	Apr. 1, 2007
§§ 1.908–1.1000	(869–062–00089–8)	60.00	Apr. 1, 2007
§§ 1.1001–1.1400	(869–060–00090–9)	61.00	Apr. 1, 2006
§§ 1.1401–1.1550	(869–060–00091–2)	58.00	Apr. 1, 2006
§§ 1.1551–End	(869–060–00092–5)	50.00	Apr. 1, 2006
2–29	(869–062–00093–6)	60.00	Apr. 1, 2007
30–39	(869–060–00094–1)	41.00	Apr. 1, 2006
40–49	(869–062–00095–2)	28.00	Apr. 1, 2007
50–299	(869–062–00096–1)	42.00	Apr. 1, 2007

Title	Stock Number	Price	Revision Date
300–499	(869–060–00097–6)	61.00	Apr. 1, 2006
500–599	(869–062–00098–7)	12.00	[6] Apr. 1, 2007
600–End	(869–062–00099–5)	17.00	Apr. 1, 2007
27 Parts:			
1–399	(869–060–00100–0)	64.00	Apr. 1, 2006
400–End	(869–062–00102–9)	18.00	Apr. 1, 2007
28 Parts:			
0–42	(869–060–00102–6)	61.00	July 1, 2006
43–End	(869–060–00103–4)	60.00	July 1, 2006
29 Parts:			
0–99	(869–060–00104–2)	50.00	July 1, 2006
100–499	(869–060–00105–1)	23.00	July 1, 2006
500–899	(869–060–00106–9)	61.00	July 1, 2006
900–1899	(869–060–00107–7)	36.00	July 1, 2006
1900–1910 (§§ 1900 to 1910.999)	(869–060–00108–5)	61.00	July 1, 2006
1910 (§§ 1910.1000 to end)	(869–060–00109–3)	46.00	July 1, 2006
1911–1925	(869–060–00110–7)	30.00	July 1, 2006
1926	(869–060–00111–5)	50.00	July 1, 2006
1927–End	(869–060–00112–3)	62.00	July 1, 2006
30 Parts:			
1–199	(869–060–00113–1)	57.00	July 1, 2006
200–699	(869–060–00114–0)	50.00	July 1, 2006
700–End	(869–060–00115–8)	58.00	July 1, 2006
31 Parts:			
0–199	(869–060–00116–6)	41.00	July 1, 2006
200–499	(869–060–00117–4)	46.00	July 1, 2006
500–End	(869–060–00118–2)	62.00	July 1, 2006
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–060–00119–1)	61.00	July 1, 2006
191–399	(869–060–00120–4)	63.00	July 1, 2006
400–629	(869–060–00121–2)	50.00	July 1, 2006
630–699	(869–060–00122–1)	37.00	July 1, 2006
700–799	(869–060–00123–9)	46.00	July 1, 2006
800–End	(869–060–00124–7)	47.00	July 1, 2006
33 Parts:			
1–124	(869–060–00125–5)	57.00	July 1, 2006
125–199	(869–060–00126–3)	61.00	July 1, 2006
200–End	(869–060–00127–1)	57.00	July 1, 2006
34 Parts:			
1–299	(869–060–00128–0)	50.00	July 1, 2006
300–399	(869–060–00129–8)	40.00	July 1, 2006
400–End & 35	(869–060–00130–1)	61.00	[8] July 1, 2006
36 Parts:			
1–199	(869–060–00131–0)	37.00	July 1, 2006
200–299	(869–060–00132–8)	37.00	July 1, 2006
300–End	(869–060–00133–6)	61.00	July 1, 2006
37	(869–060–00134–4)	58.00	July 1, 2006
38 Parts:			
0–17	(869–060–00135–2)	60.00	July 1, 2006
18–End	(869–060–00136–1)	62.00	July 1, 2006
39	(869–060–00137–9)	42.00	July 1, 2006
40 Parts:			
1–49	(869–060–00138–7)	60.00	July 1, 2006
50–51	(869–060–00139–5)	45.00	July 1, 2006
52 (52.01–52.1018)	(869–060–00140–9)	60.00	July 1, 2006
52 (52.1019–End)	(869–060–00141–7)	61.00	July 1, 2006
53–59	(869–060–00142–5)	31.00	July 1, 2006
60 (60.1–End)	(869–060–00143–3)	58.00	July 1, 2006
60 (Apps)	(869–060–00144–7)	57.00	July 1, 2006
61–62	(869–060–00145–0)	45.00	July 1, 2006
63 (63.1–63.599)	(869–060–00146–8)	58.00	July 1, 2006
63 (63.600–63.1199)	(869–060–00147–6)	50.00	July 1, 2006
63 (63.1200–63.1439)	(869–060–00148–4)	50.00	July 1, 2006
63 (63.1440–63.6175)	(869–060–00149–2)	32.00	July 1, 2006
63 (63.6580–63.8830)	(869–060–00150–6)	32.00	July 1, 2006
63 (63.8980–End)	(869–060–00151–4)	35.00	July 1, 2006
64–71	(869–060–00152–2)	29.00	July 1, 2006
72–80	(869–060–00153–1)	62.00	July 1, 2006
81–85	(869–060–00154–9)	60.00	July 1, 2006
86 (86.1–86.599–99)	(869–060–00155–7)	58.00	July 1, 2006
86 (86.600–1–End)	(869–060–00156–5)	50.00	July 1, 2006
87–99	(869–060–00157–3)	60.00	July 1, 2006
100–135	(869–060–00158–1)	45.00	July 1, 2006
136–149	(869–060–00159–0)	61.00	July 1, 2006
150–189	(869–060–00160–3)	50.00	July 1, 2006
190–259	(869–060–00161–1)	39.00	July 1, 2006
260–265	(869–060–00162–0)	50.00	July 1, 2006
266–299	(869–060–00163–8)	50.00	July 1, 2006
300–399	(869–060–00164–6)	42.00	July 1, 2006
400–424	(869–060–00165–4)	56.00	July 1, 2006
425–699	(869–060–00166–2)	61.00	July 1, 2006
700–789	(869–060–00167–1)	61.00	July 1, 2006
790–End	(869–060–00168–9)	61.00	July 1, 2006
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–060–00169–7)	24.00	July 1, 2006
101	(869–060–00170–1)	21.00	[8] July 1, 2006
102–200	(869–060–00171–9)	56.00	July 1, 2006
201–End	(869–060–00172–7)	24.00	July 1, 2006
42 Parts:			
1–399	(869–060–00173–5)	61.00	Oct. 1, 2006
400–413	(869–060–00174–3)	32.00	Oct. 1, 2006
414–429	(869–060–00175–1)	32.00	Oct. 1, 2006
430–End	(869–060–00176–0)	64.00	Oct. 1, 2006
43 Parts:			
1–999	(869–060–00177–8)	56.00	Oct. 1, 2006
1000–end	(869–060–00178–6)	62.00	Oct. 1, 2006
44	(869–060–00179–4)	50.00	Oct. 1, 2006
45 Parts:			
1–199	(869–060–00180–8)	60.00	Oct. 1, 2006
200–499	(869–060–00181–6)	34.00	Oct. 1, 2006
500–1199	(869–060–00182–4)	56.00	Oct. 1, 2006
1200–End	(869–060–00183–2)	61.00	Oct. 1, 2006
46 Parts:			
1–40	(869–060–00184–1)	46.00	Oct. 1, 2006
41–69	(869–060–00185–9)	39.00	Oct. 1, 2006
70–89	(869–060–00186–7)	14.00	Oct. 1, 2006
90–139	(869–060–00187–5)	44.00	Oct. 1, 2006
140–155	(869–060–00188–3)	25.00	Oct. 1, 2006
156–165	(869–060–00189–1)	34.00	Oct. 1, 2006
166–199	(869–060–00190–5)	46.00	Oct. 1, 2006
200–499	(869–060–00191–3)	40.00	Oct. 1, 2006
500–End	(869–060–00192–1)	25.00	Oct. 1, 2006
47 Parts:			
0–19	(869–060–00193–0)	61.00	Oct. 1, 2006
20–39	(869–060–00194–8)	46.00	Oct. 1, 2006
40–69	(869–060–00195–6)	40.00	Oct. 1, 2006
70–79	(869–060–00196–4)	61.00	Oct. 1, 2006
80–End	(869–060–00197–2)	61.00	Oct. 1, 2006
48 Chapters:			
1 (Parts 1–51)	(869–060–00198–1)	63.00	Oct. 1, 2006
1 (Parts 52–99)	(869–060–00199–9)	49.00	Oct. 1, 2006
2 (Parts 201–299)	(869–060–00200–6)	50.00	Oct. 1, 2006
3–6	(869–060–00201–4)	34.00	Oct. 1, 2006
7–14	(869–060–00202–2)	56.00	Oct. 1, 2006

Title	Stock Number	Price	Revision Date
15–28	(869–060–00203–1)	47.00	Oct. 1, 2006
29–End	(869–060–00204–9)	47.00	Oct. 1, 2006
49 Parts:			
1–99	(869–060–00205–7)	60.00	Oct. 1, 2006
100–185	(869–060–00206–5)	63.00	Oct. 1, 2006
186–199	(869–060–00207–3)	23.00	Oct. 1, 2006
200–299	(869–060–00208–1)	32.00	Oct. 1, 2006
300–399	(869–060–00209–0)	32.00	Oct. 1, 2006
400–599	(869–060–00210–3)	64.00	Oct. 1, 2006
600–999	(869–060–00211–1)	19.00	Oct. 1, 2006
1000–1199	(869–060–00212–0)	28.00	Oct. 1, 2006
1200–End	(869–060–00213–8)	34.00	Oct. 1, 2006
50 Parts:			
1–16	(869–060–00214–6)	11.00	[9] Oct. 1, 2006
17.1–17.95(b)	(869–060–00215–4)	32.00	Oct. 1, 2006
17.95(c)–end	(869–060–00216–2)	32.00	Oct. 1, 2006
17.96–17.99(h)	(869–060–00217–1)	61.00	Oct. 1, 2006
17.99(i)–end and 17.100–end	(869–060–00218–9)	47.00	[9] Oct. 1, 2006
18–199	(869–060–00219–7)	50.00	Oct. 1, 2006
200–599	(869–060–00220–1)	45.00	Oct. 1, 2006
600–659	(869–060–00221–9)	31.00	Oct. 1, 2006
660–End	(869–060–00222–7)	31.00	Oct. 1, 2006
CFR Index and Findings Aids	(869–062–00050–2)	62.00	Jan. 1, 2007
Complete 2007 CFR set		1,389.00	2007
Microfiche CFR Edition:			
Subscription (mailed as issued)		332.00	2007
Individual copies		4.00	2007
Complete set (one-time mailing)		332.00	2006
Complete set (one-time mailing)		325.00	2005

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2005, through January 1, 2006. The CFR volume issued as of January 1, 2005 should be retained.

[5] No amendments to this volume were promulgated during the period January 1, 2006, through January 1, 2007. The CFR volume issued as of January 6, 2006 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2006. The CFR volume issued as of April 1, 2000 should be retained.

[7] No amendments to this volume were promulgated during the period April 1, 2005, through April 1, 2006. The CFR volume issued as of April 1, 2005 should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 2005, through July 1, 2006. The CFR volume issued as of July 1, 2005 should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 2005, through October 1, 2006. The CFR volume issued as of October 1, 2005 should be retained.