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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 7 CFR Part 318

**[Docket No. 01–042–3]**

### Interstate Movement of Gardenia From Hawaii

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule; correction.

**SUMMARY:** In final rule published in the **Federal Register** on February 5, 2003, we amended the Hawaiian fruits and vegetables regulations to provide for the movement of cut blooms of gardenia from Hawaii. The final rule contained errors in the **SUPPLEMENTARY INFORMATION** section and in the rule portion. This document corrects those errors.

**EFFECTIVE DATE:** March 7, 2003.

**FOR FURTHER INFORMATION CONTACT:** Ms. Susan G. Dublinski, Import/Export Specialist, Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; (301) 734–4312.

**SUPPLEMENTARY INFORMATION:** In a final rule published in the **Federal Register** on February 5, 2003 (68 FR 5800–5802, Docket No. 01–042–2), we amended the Hawaiian fruits and vegetables regulations in 7 CFR part 318 to provide for the interstate movement of cut blooms of gardenia from Hawaii under certain conditions. The movement of cut blooms of gardenia had been prohibited due to gardenia's status as a host of green scale (Coccus viridis), also known as green coffee scale, a destructive plant pest. In the Supplementary Information section of the final rule, we incorrectly identified green scale as *Coccus viridus.* Therefore, we are correcting the error in the **SUPPLEMENTARY INFORMATION** section of the final rule by replacing *Coccus viridus* with *Coccus viridis.*

Under the rule, gardenia growers in Hawaii who wish to move cut blooms of gardenia interstate from Hawaii would be able to do so if the gardenias were produced in a growing area determined by an inspector to be free of green scale and to meet other requirements, including the establishment of a buffer area around the gardenia production area. This buffer area must be determined free of all green scale host plants listed in § 318.13–4j(b).

Ginger (Alpinia purpurata) and *Pluchea indica* (a weed introduced into Hawaii) are known green scale host plants and, consequently, are prohibited in the buffer area. In the rule portion of the final rule, we incorrectly identified ginger as ''*Alpinia purpurata*'' and *Pluchea indica* as ''*Pluto indicia.*'' Therefore, in order for the regulations to accurately identify these specific hosts, we are correcting § 318.13–4j(b) in the final rule by replacing *Alpina purpurata* with *Alpinia purpurata* and *Pluto indicia* with *Pluchea indica.*

**§ 318.13–4; [Corrected]**

In FR Doc. 03–2683, published on February 5, 2003 (68 FR 5800–5802), make the following corrections:

1. On page 5801, in the first column, in line 31, correct ''*(Coccus viridus)*'' to read ''*(Coccus viridis)*''.

2. On page 5802, in the third column, in § 318.13–4j, paragraph (b), correct ''*(Alpina purpurata)*'' to read ''*(Alpinia purpurata)*'' and correct ''*Pluto indicia*'' to read ''*Pluchea indica*''.

Done in Washington, DC, this 7th day of March, 2003.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 03–6058 Filed 3–12–03; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. 2001–SW–53–AD; Amendment 39–13079; AD 2003–05–03]**

**RIN 2120–AA64**

### Airworthiness Directives; Bell Helicopter Textron Canada Model 407 Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD) for the specified Bell Helicopter Textron Canada (Bell) model helicopters that requires preflight checking and repetitively inspecting for a crack in certain tailbooms that have not been redesigned and replacing the tailboom if a crack is found; modifying and re-identifying certain tailbooms and installing an improved horizontal stabilizer assembly; and assigning a 5,000 hour time-in-service (TIS) life limit. This amendment is prompted by cracking discovered in other areas of certain tailbooms and introduction of a redesigned tailboom with a chemically milled skin, which does not require the current inspections. The actions specified by this AD are intended to prevent separation of the tailboom and subsequent loss of control of the helicopter.

**DATES:** Effective April 17, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 17, 2003.

**ADDRESSES:** The service information referenced in this AD may be obtained from Bell Helicopter Textron Canada, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Sharon Miles, Aviation Safety Engineer,

FAA, Rotorcraft Directorate, Regulations Group, Fort Worth, Texas 76193–0111, telephone (817) 222–5122, fax (817) 222–5961.

**SUPPLEMENTARY INFORMATION:** On March 21, 2000, the FAA issued AD 2000–06–10, Amendment 39–11651 (65 FR 16804, March 30, 2000), to require preflight checking and repetitively inspecting the tailboom for a crack and replacing the tailboom if a crack is found. That action was prompted by four reports of cracks on the tailboom in the area of the horizontal stabilizer. The requirements of that AD were intended to prevent separation of the tailboom and subsequent loss of control of the helicopter. Next, a proposal to amend 14 CFR part 39 to include an AD for Bell Model 407 helicopters was published in the **Federal Register** on January 31, 2002 (67 FR 4685). That NPRM would have required preflight checking and repetitively inspecting for a crack in certain tailbooms that have not been redesigned and replacing the tailboom if a crack is found. It further proposed that installing tailboom, P/N 407–030–801–201, would constitute terminating action for the requirements of that AD.

Since the issuance of that NPRM on January 31, 2002 (67 FR 4685), the manufacturer has issued Bell Helicopter Textron Alert Service Bulletin (ASB) No. 407–99–26, Revision C, dated February 28, 2002, that addresses inspection procedures for certain tailbooms. The manufacturer also issued Bell Helicopter Textron ASB No. 407–01–48, Revision B, dated April 25, 2002, that details the modification and re-identification of those certain tailbooms, assigns a life limit, and details new inspection procedures for those re-identified tailbooms. Additionally, ASB 407–01–48 assigns a life limit and details new inspection procedures for another part-numbered tailboom that was modified by the manufacturer. Further, in addition to the redesigned tailboom, P/N 407–030–801–201, referenced in the NPRM, Bell has at least one additional redesigned tailboom, P/N 407–030–801–203, for these helicopters. Transport Canada, which is the airworthiness authority for Canada, has issued a revised AD No. CF–1999–17R2, dated April 5, 2002, to address these changed requirements.

After reviewing comments received in response to that proposal as well as updated service information from the manufacturer, on November 14, 2002 (67 FR 68952), the FAA published a supplemental notice in the **Federal Register** to propose mandating daily pre-flight checks and initial 25-hour TIS inspections with recurring 50 hour TIS inspections for the tailbooms, P/N 407–030–801–101 and –105, until they are modified and re-identified. Once modified and re-identified as P/N 407–530–014–101 and –103, respectively, the FAA proposed to mandate the 150-hour TIS inspection and assign a 5,000-hour TIS life limit. The 150-hour TIS inspection and 5,000 hour life limit also applies to the tailboom, P/N 407–030–801–107. Additionally, the cite to tailboom, P/N 407–030–801–201, as a terminating action was removed since the installation of other redesigned tailbooms may also effectively remove a helicopter from the applicability of this proposal, thereby constituting a terminating action for the requirements of this AD.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Two commenters state that the instructions need to be clear regarding the assignment of the life limit. The FAA agrees and has changed paragraph (d) of the AD to clarify the tailboom life limit. For the modified tailbooms, P/N 407–530–014–101 and P/N 407–530–014–103, 5,000 hours TIS since modified and installed is the life limit. The life limit for tailboom, P/N 407–030–801–107, is 5,000 hours since new (initially installed on any helicopter).

One commenter states that the proposed compliance date may be too short. Additionally, the commenter points out an incorrect reference in the preamble discussion to the part number tailboom cited for use as a terminating action. The FAA agrees; P/N 407–030–801–101 cited in the discussion should have been P/N 407–030–801–201. Also, the FAA agrees that the compliance time was too short. Because the compliance time cited in the proposal was ''January 31, 2003'' and that date has passed, the required compliance time for paragraph (c) of the AD is changed to ''within 30 days.''

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 284 helicopters of U.S. registry will be affected by this AD, that it will take approximately 3.5 work hours per helicopter to accomplish the initial inspections, 1.5 work hours per helicopter to accomplish the recurring inspections, and 18 work hours per helicopter to accomplish the modification, and that the average labor rate is $60 per work hour. Required parts will cost approximately $1,244 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $3,254 per helicopter, or $924,136, assuming all U.S. registered helicopters are required to be modified and initially inspected, and have 8 repetitive inspections per year. In its service information, under certain conditions, the manufacturer offers a ''special'' warranty for parts needed for modifying tailbooms, P/N 407–030–801–101 and –105, and a labor allowance of $480.

The regulations adopted herein will 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

**2003–05–03 Bell Helicopter Textron Canada:** Amendment 39–13079. Docket No. 2001–SW–53–AD. Supersedes AD 2000–06–10, Docket No. 99–SW–75–AD, Amendment 39–11651.

*Applicability:* Model 407 helicopters, serial numbers 53000 through 53475, with tailboom, part number (P/N) 407–030–801–101, –105 or–107, or P/N 407–530–014–101 or –103, (re-identified in accordance with Bell Helicopter Textron (Bell) Alert Service Bulletin (ASB) 407–01–48, Revision B, dated April 25, 2002), installed, certificated in any category.

**Note 1:** This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (h) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated.

To prevent separation of the tailboom and subsequent loss of control of the helicopter, accomplish the following:

| Applicable tailboom | Compliance time | Actions | In accordance with |
|---|---|---|---|
| (a) Tailboom, P/N 407–030–801–101 and –105, that have not been modified in accordance with Bell ASB 407–01–048, Revision B, dated April 25, 2002. | Before the first flight of each day | Visually check the tailboom for cracks. An owner/operator (pilot) holding at least a private pilot certificate may perform the visual check required by this paragraph, but must enter compliance with this paragraph into the helicopter records in accordance with 14 CFR 43.11 and 91.417(a)(2)(v). | Figure 1 of this AD. |
| (b) Tailboom, P/N 407–030–801–101 and –105, that have 600 or more hours TIS and have not been modified in accordance with Bell ASB 407–01–48, Revision B, dated April 25, 2002. | Within 25 hours time-in-service (TIS), and thereafter at intervals not to exceed 50 hours TIS. | Visually inspect the tailboom for cracks using a 10x or higher magnifying glass. | Part II of the Accomplishment Instructions of Bell ASB 407–99–26, Revision C, dated February 28, 2002, except contacting Bell is not required. |
| (c) Tailboom, P/N 407–030–801–101 and –105. | Within 600 hours TIS, but not later than 30 days, unless previously accomplished. | Modify and re-identify tailbooms as P/N 407–530–014–101 and –103, respectively, and install improved horizontal stabilizer assembly, P/N 407–023–800–ALL. | Parts I and III of the Accomplishment Instructions in Bell ASB 407–01–48, Revision B, dated April 25, 2002, and Bell Technical Bulletin No. 407–01–33, dated August 29, 2001, except contacting Bell is not required. |
| (d) Tailboom, P/N 407–530–014–101 and –103; and P/N 407–030–801–107. | Before further flight after the tailboom is modified and re-identified, unless previously accomplished. | Create a historical service record sheet and assign a life limit of 5,000 hours TIS since modification, re-identification, and installation of tailboom, P/N 407–530–014–101 or –103, on any helicopter, or initial installation of P/N 407–030–801–107 on any helicopter. | Part IV of the Accomplishment Instructions in Bell ASB 407–01–48, Revision B, dated April 25, 2002. |
| (e) Tailboom, P/N 407–530–014–101 and 103; and P/N 407–030–801–107. | Within 150 hours TIS after modification, or within 150 hours TIS since new, and thereafter at intervals not to exceed 150 hours TIS. | Inspect the tailboom for a crack ... | Parts IV and V of the Accomplishment Instructions in Bell ASB 407–01–48, Revision B, dated April 25, 2002. |
| (f) All applicable part-numbered tailbooms. | Before further flight ..... | If a crack is found, replace the tailboom. | The applicable maintenance manual. |

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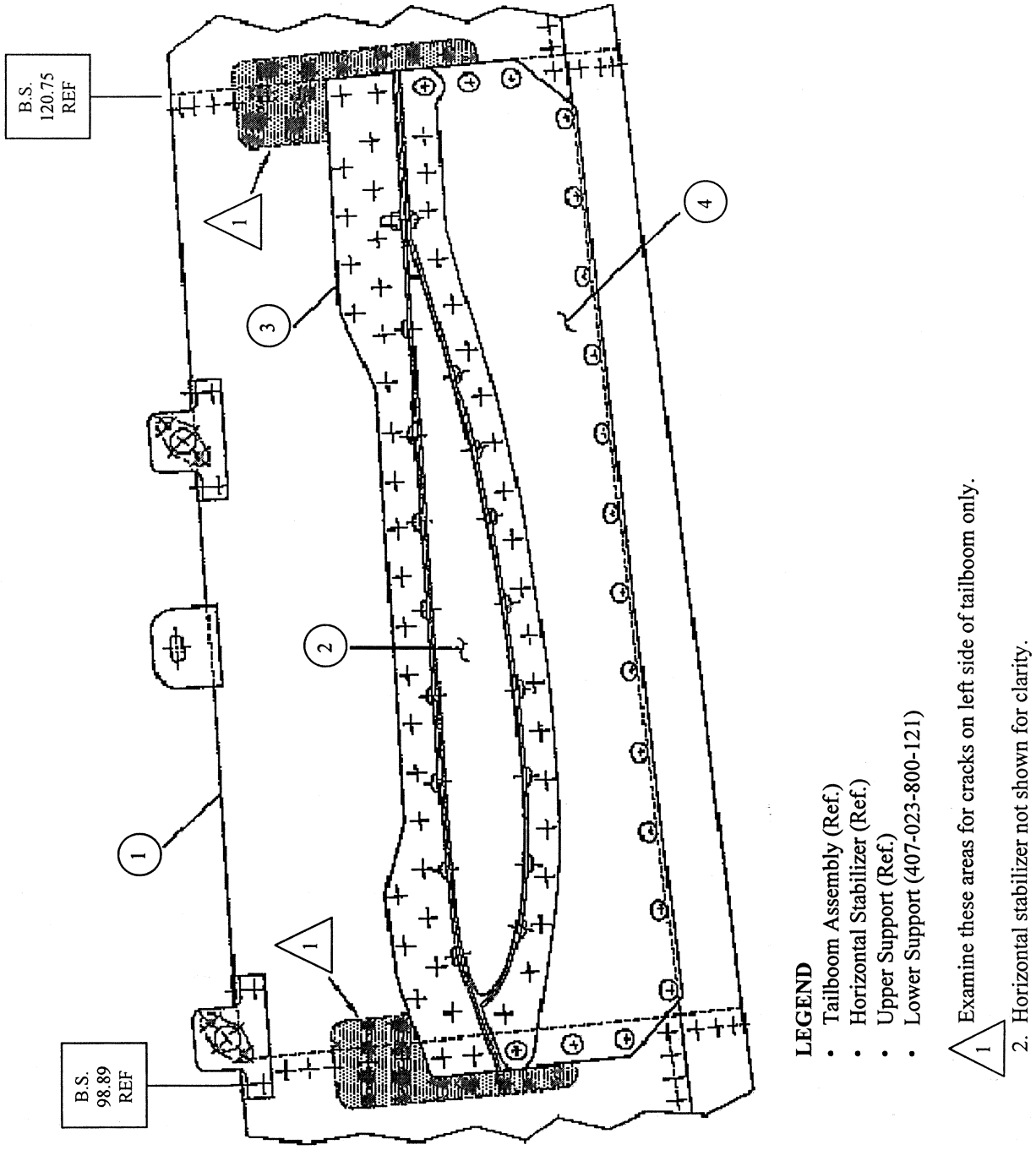


Figure 1. Preflight Check of the Tailboom

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(g) This AD revises the helicopter Airworthiness Limitations section of the maintenance manual by establishing a new retirement life for the tailboom, P/N 407–530–014–101 and –103, and P/N 407–030–801–107 of 5,000 hours TIS.

(h) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(i) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(j) The inspections shall be done in accordance with Part II of the Accomplishment Instructions in Bell Helicopter Textron Alert Service Bulletin No.

407–99–26, Revision C, dated February 28, 2002. The modifications and re-identifications shall be accomplished in accordance with Bell Helicopter Textron Technical Bulletin No. 407–01–33, dated August 29, 2001, and Parts I and III of the Accomplishment Instructions in Bell Helicopter Textron Alert Service Bulletin 407–01–48, Revision B, dated April 25, 2002. The creation of historical service record sheets and inspections shall be done in accordance with Parts IV and V of the Accomplishment Instructions in Bell Helicopter ASB 407–01–48, Revision B, dated April 25, 2002. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bell Helicopter Textron Canada, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4, telephone (450) 437–2862 or (800) 363–8023, fax (450) 433–0272. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(k) This amendment becomes effective on April 17, 2003.

**Note 3:** The subject of this AD is addressed in Transport Canada (Canada) AD No. CF–1999–17R2, dated April 5, 2002.

Issued in Fort Worth, Texas, on March 3, 2003.

**David A. Downey,**

*Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 03–5576 Filed 3–12–03; 8:45 am]

**BILLING CODE 4910–13–P**

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2002–NE–27–AD; Amendment 39–13083; AD 2003–05–07]**

**RIN 2120–AA64**

## Airworthiness Directives; Pratt & Whitney JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR Turbofan Engines

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment adopts a new airworthiness directive (AD), that is applicable to Pratt & Whitney (PW) JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines. This amendment requires removal from service of certain part number (P/N) 3rd–4th and 4th–5th stage compressor rotor spacer assemblies and incorporation of a new tierod retention configuration. This amendment is prompted by two reports of uncontained failure of JT8D turbofan engines, caused by turbine rotor overspeed resulting from first and second stage fan section separation from the low pressure compressor (LPC). The actions specified by this AD are intended to prevent first and second stage fan section separation from the LPC, resulting in turbine rotor overspeed, uncontained engine failure, and damage to the airplane.

**DATES:** Effective April 17, 2003. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 17, 2003.

**ADDRESSES:** The service information referenced in this AD may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–8770; fax (860) 565–4503. This information may be examined, by appointment, at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7175; fax (781) 238–7199.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that is applicable to PW JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines was published in the **Federal Register** on November 15, 2002, (67 FR 69152). That action proposed to require removal from service of certain P/N 3rd–4th and 4th–5th stage compressor rotor spacer assemblies and incorporation of a new tierod retention configuration in accordance with PW Service Bulletin (SB) No. JT8D 6429, dated August 23, 2002.

### Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

### Agreement With Proposal as Written

The National Transportation Safety Board and one other commenter agree with the proposal as written.

### Compliance With Referenced Service Bulletins

One commenter states that compliance with PW SBs 5408, 5719, and 5734 should be considered direct compliance to the proposed rule in place of PW SB 6429, dated August 23, 2002. The commenter believes that these three service bulletins offer an equivalent level of safety to that of PW SB 6429. Further, the commenter is concerned that the new PW SB 6429 may introduce new failure modes.

The FAA does not agree. The proposed rule is worded such that the intents of SBs 5409, 5719, and 5734 are contained in paragraph (a) of the final rule. This wording was chosen at the request of the Air Transport Association (ATA) to facilitate easier compliance by operators. However, while the modifications identified by these bulletins reduce the probability of encountering a tierod fracture and some operators may not have experienced one since incorporating the bulletins, they do not prevent the fractures completely. The FAA has received reports from PW of tierod fractures occurring after incorporating SBs 5409, 5719, and 5734. Accordingly, PW has issued SB JT8D 6429, dated August 23, 2002, which adds a tierod retention feature to prevent the escape of the fractured end of the tierod which can lead to separation of the first and second stage fan sections from the rear stages of the LPC and a subsequent uncontained engine failure. Further, the new design features in question have been used on other engines with similar tierod configurations. The new tierods meet all of the airworthiness standards required for certification. Proven design standards used for the new retention feature have demonstrated to the FAA that no new failure modes will be introduced into the field.

### Lack of Enforcement of Acceptable Maintenance Practices and Financial Burden

One commenter states that the rule ignores enforcement of acceptable, pertinent maintenance practices and adds monetary burden to all operators, without regard to disciplined adherence to PW's or operator's approved maintenance program.

The FAA does not agree. The FAA has identified an unsafe condition that exists on a type certified product. The actions identified to correct that condition are manufacturer's maintenance recommendations. The FAA is required to mandate these recommendations in order to correct the unsafe condition. Operators are still

afforded the opportunity to develop an alternative plan to correct the unsafe condition under the provisions of paragraph (d) of this AD. Many operators already incorporate the requirements in this AD under their approved maintenance program, therefore their monetary burden should be minimal.

### Request for Alternate Compliance Time and Eliminate Time Restrictions

One commenter asks that the AD be written to allow AD compliance during LPC module heavy maintenance, when at piece-part level, without time restrictions.

The FAA does not agree. The proposal currently requires the compliance at LPC accessibility which is defined as removal of the affected parts at the piece-part level. No time restrictions are included in the AD. If there are specific aspects of an operator's maintenance plan that make this definition an unusual burden, the operator should propose an alternative incorporation plan under the provisions of paragraph (d) of the AD.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

### Economic Analysis

There are approximately 4,180 PW JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines of the affected design in the worldwide fleet. The FAA estimates that 1,800 engines installed on aircraft of U.S. registry will be affected by this AD, that it will take approximately 41 work hours per engine to perform the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $3,600 per engine. Based on these figures, the total cost of the AD to U.S. operators is estimated to be $10,908,000.

### Regulatory Analysis

This final rule does not have federalism implications, as defined in Executive Order 13132, because it 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this final rule.

For the reasons discussed above, I certify that this action (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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

**2003–05–07 Pratt & Whitney:** Amendment 39–13083. Docket No. 2002–NE–27–AD.

*Applicability:* This airworthiness directive (AD) is applicable to Pratt & Whitney (PW) JT8D–1, –1A, –1B, –7, –7A, –7B, –9, –9A, –11, –15, –15A, –17, –17A, –17R, and –17AR turbofan engines. These engines are installed on, but not limited to Boeing 727 and 737 series, and McDonnell Douglas DC–9 series airplanes.

**Note 1:** This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Compliance with this AD is required as indicated, unless already done.

To prevent first and second stage fan section separation from the low pressure compressor (LPC), resulting in turbine rotor overspeed, uncontained engine failure, and damage to the airplane, do the following:

(a) At the next accessibility of the LPC, do the following:

(1) Remove from service 3rd–4th stage compressor rotor spacer assemblies part numbers (P/Ns) 479927, 522194, 583385, 656814, 656815, 660649, 660655, 716851, 716853, 716854, 762140, 762145, 762271, 762468, 789554, and 789752 and replace with a serviceable part.

(2) Remove from service 4th–5th stage compressor rotor spacer assemblies P/Ns 479929, 522196, 656816, 656817, 660650, 660656, 716855, 762138, and 762142 and replace with a serviceable part.

(3) Remove from service 4th–5th stage compressor rotor spacer assemblies P/N 628778 that do not incorporate service bulletin (SB) 5409, and replace with a serviceable part.

**Note 2:** Information on modifying parts listed in paragraphs (a)(1), (a)(2), and (a)(3) of this AD into servicable parts is contained in PW SBs No. 5409, SB No. 5716, and SB No. 5734.

(4) Incorporate new tierods, retaining rings, 2nd stage compressor air seal or spacer assembly, flat washers and tierod nuts in the LPC in accordance with the Accomplishment Instructions of PW SB JT8D 6429, dated August 23, 2002.

(b) After the effective date of this AD, do not install 3rd–4th or 4th–5th stage compressor rotor spacer assemblies listed in paragraphs (a)(1), (a)(2), and (a)(3) of this AD into any engine.

#### Definition

(c) For the purpose of this AD, accessibility means removal of the LPC from the engine and disassembly that provides piece-part exposure to the parts listed in paragraph (a) of this AD.

#### Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

#### Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done.

#### Documents That Have Been Incorporated By Reference

(f) The actions must be done in accordance with Pratt & Whitney Service Bulletin JT8D 6429, dated August 23, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR

part 51. Copies may be obtained from Pratt & Whitney, 400 Main St., East Hartford, CT 06108; telephone (860) 565–8770; fax (860) 565–4503. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Effective Date**

(g) This amendment becomes effective on April 17, 2003.

Issued in Burlington, Massachusetts, on March 4, 2003.

**Jay J. Pardee,**

*Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 03–5692 Filed 3–12–03; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF DEFENSE

## Office of the Secretary

## 32 CFR Part 199

**RIN –0720–AA74**

## TRICARE; Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Appeals and Hearings Procedures, Formal Review

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Interim Final Rule; administrative corrections.

**SUMMARY:** This document makes administrative corrections to the 32 CFR part 199, section 199.10, ''Appeal and Hearing Procedures.'' These corrections include revising § 199.10, adding paragraphs (c)(1) through (c)(5), and making other minor editorial changes.

**DATES:** Forward comments on or before May 12, 2003.

**ADDRESSES:** Forward comments to Medical Benefits and Reimbursement Systems, TRICARE Management Activity, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

**FOR FURTHER INFORMATION CONTACT:** Gail L. Jones, Medical Benefits and Reimbursement Systems, TRICARE Management Activity, telephone (303) 676–3401.

**SUPPLEMENTARY INFORMATION:** Paragraphs (c)(1) through (c)(5) were inadvertently omitted when the July 1, 1991 edition of the 32 CFR was published. The discovery that the formal review process was missing from § 199.10 occurred at the time that TRICARE was tasked to promulgate an appeal process for TRICARE Claimcheck denials.

This correction to § 199.10 is necessary to provide the required procedures to any party to an initial determination or reconsideration determination made by the CHAMPUS contractor and who may want to request a formal review.

Executive Order 12866 requires certain regulatory assessments for any ''significant regulatory action'' defined as one, which would result in an annual effect on the economy of $100 million or more, or have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities.

This rule has been designated as significant rule and has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866. The Department of Defense certifies that this interim final rule would not have a significant impact on small business entities.

This interim final rule will not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3511).

**List of Subjects in 32 CFR Part 199**

Claims, Health insurance, Individuals with disabilities, Dental Health, Military personnel.

Accordingly, 32 CFR Part 199 is amended as follows:

## PART 199—[AMENDED]

1. The authority citation for Part 199 continues to read as follows:

**Authority:** 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Section 199.10 is amended by revising paragraph (b) introductory text, and revising paragraph (c) to read as follows:

### § 199.10 Appeals and Hearings Procedures.

* * * * *

(b) *Reconsideration.* Any party to the initial determination made by the CHAMPUS contractor, or a CHAMPUS peer review organization may request reconsideration.

* * * * *

(c) *Formal review.* Except as explained in this paragraph, any party to an initial determination made by OCHAMPUS, or a reconsideration determination made by the CHAMPUS contractor, may request a formal review by OCHAMPUS if the party is dissatisfied with the initial or reconsideration determination unless the initial or reconsideration determination is final under paragraph (b)(5) of this section; involves the sanctioning of a provider by the exclusion, suspension or termination of authorized provider status; involves a written decision issued pursuant to § 199.9(h)(1)(iv)(A) regarding the temporary suspension of claims processing; or involves a reconsideration determination by a CHAMPUS peer review organization. A hearing, but not a formal review level of appeal, may be available to a party to an initial determination involving the sanctioning of a provider or to a party to a written decision involving a temporary suspension of claims processing. A beneficiary (or an authorized representative of a beneficiary), but not a provider (except as provided in § 199.15), may request a hearing, but not a formal review, of a reconsideration determination made by a CHAMPUS peer review organization.

(1) *Requesting a formal review.* (i) *Written request required.* The request must be in writing, shall state the specific matter in dispute, shall include copies of the written determination (notice of reconsideration determination or OCHAMPUS initial determination) being appealed, and shall include any additional information or documents not submitted previously.

(ii) *Where to file.* The request shall be submitted to the Chief, Office of Appeals and Hearings, TRICARE Management Activity, 16401 East Centretech Parkway, Auroa, Colorado 80011–9066.

(iii) *Allowed time to file.* The request shall be mailed within 60 days after the date of the notice of the reconsideration determination or OCHAMPUS initial determination being appealed.

(iv) *Official filing date.* A request for a formal review shall be deemed filed on the date it is mailed and postmarked. If the request does not have a postmark, it shall be deemed filed on the date received by OCHAMPUS.

(2) *The formal review process.* The purpose of the formal review is to determine whether the initial determination or reconsideration determination was made in accordance with law, regulation, policies, and guidelines in effect at the time the care was provided or requested or at the time of the initial determination, reconsideration, or formal review decision involving a provider request for approval as an authorized CHAMPUS provider. The formal review is performed by the Chief, Office of Appeals and Hearings, OCHAMPUS, or

a designee, and is a thorough review of the case. The formal review determination shall be based on the information, upon which the initial determination and/or reconsideration determination was based, and any additional information the appealing party may submit or OCHAMPUS may obtain.

(3) *Timeliness of formal review determination.* The Chief, Office of Appeals and Hearings, OCHAMPUS, or a designee normally shall issue the formal review determination no later than 90 days from the date of receipt of the request for formal review by the OCHAMPUS.

(4) *Notice of formal review determination.* The Chief, Office of Appeals and Hearings, OCHAMPUS, or a designee shall issue a written notice of the formal review determination to the appealing party at his or her last known address. The notice of the formal review determination must contain the following elements:

(i) A statement of the issue or issues under appeal.

(ii) The provisions of law, regulation, policies, and guidelines that apply to the issue or issues under appeal.

(iii) A discussion of the original and additional information that is relevant to the issue or issues under appeal.

(iv) Whether the formal review upholds the prior determination or determinations or reverses the prior determination or determinations in whole or in part and the rationale for the action.

(v) A statement of the right to request a hearing in any case when the formal review determination is less than fully favorable, the issue is appealable, and the amount in dispute is $300 or more.

(5) *Effect of formal review determination.* The formal review determination is final if one or more of the following exist:

(i) The issue is not appealable. (See paragraph (a)(6) of this section.)

(ii) The amount in dispute is less than $300. (See paragraph (a)(7) of this section.)

(iii) Appeal rights have been offered but a request for hearing is not received by OCHAMPUS within 60 days of the date of the notice of the formal review determination.

* * * * *

Dated: March 7, 2003.

**L.M. Bynum,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 03–5954 Filed 3–12–03; 8:45 am]

BILLING CODE 5001–08–M

## DEPARTMENT OF TRANSPORTATION

## Saint Lawrence Seaway Development Corporation

## 33 CFR Part 401

**[Docket No. SLSDC 2002–13698]**

**RIN 2135–AA15**

## Seaway Regulations and Rules: Automatic Identification System

**AGENCY:** Saint Lawrence Seaway Development Corporation, DOT.

**ACTION:** Final rule; correction.

**SUMMARY:** In the Saint Lawrence Seaway Development Corporation (SLSDC) final rule amending the Seaway regulations and rules (33 CFR part 401) published in the **Federal Register** on February 28, 2003 (68 FR 9549), an inadvertent error was made in the heading of the new § 401.20. This document corrects that error.

**DATES:** Effective on March 25, 2003.

**FOR FURTHER INFORMATION CONTACT:** Marc C. Owen, Chief Counsel, Saint Lawrence Seaway Development Corporation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–6823.

**SUPPLEMENTARY INFORMATION:** In the Saint Lawrence Seaway Development Corporation (SLSDC) final rule amending the Seaway regulations and rules (33 CFR part 401) published in the **Federal Register** on February 28, 2003 (68 FR 9549), an inadvertent error was made in the heading of the new § 401.20. In the heading, the word ''Automated'' should have been ''Automatic.'' This correction makes that change.

In rule FR Doc. 03–4740 published in the **Federal Register** on February 28, 2003 (68 FR 9549), make the following correction:

1. On page 9551, in the heading of the new § 401.20, remove ''Automated'' and add in its place ''Automatic''.

Issued in Washington, DC on March 10, 2003.

Saint Lawrence Seaway Development Corporation.

**Marc C. Owen,**

*Chief Counsel.*

[FR Doc. 03–6048 Filed 3–12–03; 8:45 am]

BILLING CODE 4910–61–P

## LIBRARY OF CONGRESS

## 36 CFR Part 704

## National Film Preservation Board; 1994–2002 Films Selected for Inclusion in the National Film Registry

**AGENCY:** National Film Preservation Board, Library of Congress.

**ACTION:** Final rule.

**SUMMARY:** The Librarian of Congress is publishing the following list of films selected from 1994–2002 for inclusion in the National Film Registry in the Library of Congress pursuant to section 103 of the National Film Preservation Act of 1996. The films are published to notify the public of the Librarian's selection of twenty-five films selected in each of these years deemed to be ''culturally, historically or aesthetically significant'' in accordance with Congress' mandate. These 225 new films join the 125 films already selected for inclusion in the Registry under section 203 of the 1992 Act, as well as previously chosen under section 3 of Pub. L. 100–446. The National Film Preservation Act of 1988. The Librarian's goal in administering the Act is to promote the preservation of all genres of film, represented by the diverse list of films selected for inclusion in the Registry, and to generate public interest in film as an art form deserving of preservation.

**EFFECTIVE DATE:** Date of Publication.

**FOR FURTHER INFORMATION CONTACT:** Steve Leggett, Staff Coordinator, The National Film Preservation Board. Telephone (202) 707–5912; telefax (202) 707–2371; email: *sleg@loc.gov.*

**SUPPLEMENTARY INFORMATION:** On August 9, 1990 (55 FR 32567), the Librarian of Congress published the list of films for 1989 for inclusion in the National Film Registry in the Library of Congress. On December 24, 1990 (55 FR 52844) the Librarian published the list of films for 1990. On September 30, 1991 (56 FR 49413) the Librarian published the list of films for 1991. On July 8, 1994 (59 FR 35034) the Librarian published the list of films for 1992 and 1993, bringing the total to 125 films selected under the 1988 and 1992 Acts. Today, the Librarian publishes the sixth-fourteenth lists of films for inclusion in the National Film Registry—twenty-five additional films selected in each year, 1994–2002, added to the films already selected.

The 1988 Act expired on September 27, 1991. The 1992 Act expired on June 26, 1996. On October 11, 1996, President Clinton signed into law the National Film Preservation Act of 1996,

reauthorizing the National Film Preservation Board for an additional seven years. The legislation [section 103(b), 2 U.S.C. 179m] requires the Librarian of Congress, in consultation with his advisory group, the National Film Preservation Board, to select up to twenty-five films per year for inclusion in the Registry. Under the 1996 Act, films are selected on the basis of their cultural, historical or aesthetic significance and they must be at least 10 years old. Films do not need to be feature length nor have had a theatrical release in order to be included.

These broad criteria allow many types of films to be eligible for inclusion in the National Film Registry. In addition, the Librarian's procedures for public participation are intended to allow the public the greatest flexibility in nominating films for inclusion. This is in keeping with the broad goals of the Librarian in administering the National Film Preservation Act to promote preservation of the complete American film heritage and to generate public interest for this cause.

**List of Subjects in 36 CFR part 704**

Labeling, Libraries, Motion pictures.

**Publication of 1994–2002 Film Titles**

In consideration of the foregoing, 36 CFR part 704 is amended in the manner set forth below.

## PART 704—NATIONAL FILM REGISTRY OF THE LIBRARY OF CONGRESS

1. The authority citation for 36 CFR part 704 continues to read as follows:

**Authority:** Public Law 104–285, 110 Stat. 3377 (2 U.S.C. 179).

## Subpart A—Films Selected for Inclusion in the National Film Registry

2. In subpart A, § 704.25 is added to read as follows:

### § 704.25 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 1994.

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 1994:

(1) The African Queen (1951)
(2) The Apartment (1960)
(3) The Cool World (1963)
(4) A Corner in Wheat (1909)
(5) E.T. The Extra-Terrestrial (1982)
(6) The Exploits of Elaine (1914)
(7) Force of Evil (1948)
(8) Freaks (1932)
(9) Hell's Hinges (1916)
(10) Hospital (1970)
(11) Invasion of the Body Snatchers (1956)
(12) The Lady Eve (1941)
(13) Louisiana Story (1948)
(14) The Manchurian Candidate (1962)
(15) Marty (1955)
(16) Meet Me in St. Louis (1944)
(17) Midnight Cowboy (1969)
(18) A Movie (1958)
(19) Pinocchio (1940)
(20) Safety Last (1923)
(21) Scarface (1932)
(22) Snow White (1933)
(23) Tabu (1931)
(24) Taxi Driver (1976)
(25) Zapruder Film (1963)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

3. In subpart A, § 704.26 is added to read as follows:

### § 704.26 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 1995.

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 1995:

(1) The Adventures of Robin Hood (1938)
(2) All That Heaven Allows (1955)
(3) American Graffiti (1973)
(4) The Band Wagon (1953)
(5) Blacksmith Scene (1893)
(6) Cabaret (1972)
(7) Chan Is Missing (1982)
(8) The Conversation (1974)
(9) The Day the Earth Stood Still (1951)
(10) El Norte (1983)
(11) Fatty's Tintype Tangle (1915)
(12) The Four Horsemen of the Apocalypse (1921)
(13) Fury (1936)
(14) Gerald McBoing Boing (1951)
(15) The Hospital (1971)
(16) Jammin' the Blues (1944)
(17) The Last of the Mohicans (1920)
(18) Manhatta (1921)
(19) North By Northwest (1959)
(20) The Philadelphia Story (1940)
(21) Rip Van Winkle (1896)
(22) Seventh Heaven (1927)
(23) Stagecoach (1939)
(24) To Fly (1976)
(25) To Kill a Mockingbird (1962)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

4. In subpart A, § 704.27 is added to read as follows:

### § 704.27 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 1996.

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 1996:

(1) The Awful Truth (1937)
(2) Broken Blossoms (1919)
(3) The Deer Hunter (1978)
(4) Destry Rides Again (1939)
(5) Flash Gordon serial (1936)
(6) The Forgotten Frontier (1931)
(7) Frank Film (1973)
(8) The Graduate (1967)
(9) The Heiress (1949)
(10) The Jazz Singer (1927)
(11) Life and Times of Rosie the Riveter (1980)
(12) M*A*S*H (1970)
(13) Mildred Pierce (1945)
(14) The Outlaw Josey Wales (1976)
(15) The Producers (1968)
(16) Pull My Daisy (1959)
(17) Road to Morocco (1942)
(18) She Done Him Wrong (1933)
(19) Shock Corridor (1963)
(20) Show Boat (1936)
(21) The Thief of Baghdad (1924)
(22) To Be Or Not To Be (1942)
(23) Topaz (1943–45) (home movie footage taken at Japanese American Internment Camp, the Topaz War Relocation Authority Center)
(24) Verbena Tragica (1939)
(25) Woodstock (1970)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

5. In subpart A, § 704.28 is added to read as follows:

### § 704.28 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 1997.

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 1997:

(1) Ben-Hur (1926)
(2) The Big Sleep (1946)
(3) The Bridge on the River Kwai (1957)
(4) Cops (1922)
(5) Czechoslovakia 1968 (1968)
(6) Grass (1925)
(7) The Great Dictator (1940)
(8) Harold and Maude (1972)
(9) Hindenburg Disaster Newsreel Footage (1937)
(10) How the West Was Won (1962)
(11) The Hustler (1961)
(12) Knute Rockne, All American (1940)
(13) The Life and Death of 9413—A Hollywood Extra (1928)
(14) The Little Fugitive (1953)

(15) Mean Streets (1973)
(16) Motion Painting No. 1 (1947)
(17) The Music Box (1932)
(18) The Naked Spur (1953)
(19) Rear Window (1954)
(20) Republic Steel Strike Riots Newsreel Footage (1937)
(21) Return of the Secaucus 7 (1980)
(22) The Thin Man (1934)
(23) Tulips Shall Grow (1942)
(24) West Side Story (1961)
(25) Wings (1927)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

6. In subpart A, § 704.29 is added to read as follows:

**§ 704.29 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 1998.**

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 1998:

(1) Bride of Frankenstein (1935)
(2) The City (1939)
(3) Dead Birds (1964)
(4) Don't Look Back (1967)
(5) Easy Rider (1969)
(6) 42nd Street (1933)
(7) From the Manger to the Cross (1912)
(8) Gun Crazy (1949)
(9) The Hitch-Hiker (1953)
(10) The Immigrant (1917)
(11) The Last Picture Show (1972)
(12) Little Miss Marker (1934)
(13) The Lost World (1925)
(14) Modesta (1956)
(15) The Ox-Bow Incident (1943)
(16) Pass the Gravy (1928)
(17) Phantom of the Opera (1925)
(18) Powers of Ten (1978)
(19) The Public Enemy (1931)
(20) Sky High (1922)
(21) Steamboat Willie (1928)
(22) Tacoma Narrows Bridge Collapse (1940)
(23) Tootsie (1982)
(24) Twelve O'Clock High (1949)
(25) ''Westinghouse Works, 1904'' (1904)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

7. In subpart A, § 704.30 is added to read as follows:

**§ 704.30 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 1999.**

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 1999:

(1) Civilization (1916)
(2) Do the Right Thing (1989)
(3) The Docks of New York (1928)
(4) Duck Amuck (1953)
(5) The Emperor Jones (1933)
(6) Gunga Din (1939)
(7) In the Land of the Head-Hunters (1914) aka In the Land of the War Canoes
(8) Jazz on a Summer's Day (1959)
(9) King: A Filmed Record . . . Montgomery to Memphis (1970)
(10) The Kiss (1896)
(11) Kiss Me Deadly (1955)
(12) Lambchops (1929)
(13) Laura (1944)
(14) Master Hands (1936)
(15) My Man Godfrey (1936)
(16) Night of the Living Dead (1968)
(17) The Plow That Broke the Plains (1936)
(18) Raiders of the Lost Ark (1981)
(19) Roman Holiday (1953)
(20) The Shop Around the Corner (1940)
(21) A Streetcar Named Desire (1951)
(22) The Ten Commandments (1956)
(23) Trance and Dance in Bali (1938–39)
(24) The Wild Bunch (1969)
(25) Woman of the Year (1942)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

8. In subpart A, § 704.31 is added to read as follows:

**§ 704.31 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 2000.**

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 2000:

(1) Apocalypse Now (1979)
(2) Dracula (1931)
(3) The Fall of the House of Usher (1928)
(4) Five Easy Pieces (1970)
(5) GoodFellas (1990)
(6) Koyaanisqatsi (1983)
(7) The Land Beyond the Sunset (1912)
(8) Let's All Go to the Lobby (1957)
(9) The Life of Emile Zola (1937)
(10) Little Caesar (1930)
(11) The Living Desert (1953)
(12) Love Finds Andy Hardy (1938)
(13) Multiple Sidosis (1970)
(14) Network (1976)
(15) Peter Pan (1924)
(16) Porky in Wackyland (1938)
(17) President McKinley Inauguration Footage (1901)
(18) Regeneration (1915)
(19) Salome (1922)
(20) Shaft (1971)
(21) Sherman's March (1986)
(22) A Star is Born (1954)
(23) The Tall T (1957)
(24) Why We Fight (series) (1943–45)
(25) Will Success Spoil Rock Hunter? (1957)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

9. In subpart A, § 704.32 is added to read as follows:

**§ 704.32 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 2001.**

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 2001:

(1) Abbott and Costello Meet Frankenstein (1948)
(2) All That Jazz (1979)
(3) All the King's Men (1949)
(4) America, America (1963)
(5) Cologne: From the Diary of Ray and Esther (1939)
(6) Evidence of the Film (1913)
(7) Hoosiers (1986)
(8) The House in the Middle (1954)
(9) It (1927)
(10) Jam Session (1942)
(11) Jaws (1975)
(12) Manhattan (1979)
(13) Marian Anderson: The Lincoln Memorial Concert (1939)
(14) Memphis Belle (1944)
(15) The Miracle of Morgan's Creek (1944)
(16) Miss Lulu Bett (1921)
(17) National Lampoon's Animal House (1978)
(18) Planet of the Apes (1968)
(19) Rose Hobart (1936)
(20) Serene Velocity (1970)
(21) The Sound of Music (1965)
(22) Stormy Weather (1943)
(23) The Tell-Tale Heart (1953)
(24) The Thin Blue Line (1988)
(25) The Thing From Another World (1951)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

10. In subpart A, § 704.33 is added to read as follows:

**§ 704.33 Films Selected for Inclusion in the National Film Registry in the Library of Congress for 2002.**

(a) The Librarian of Congress, Dr. James H. Billington, after consultation with the National Film Preservation Board, registers these films in the National Film Registry within the Library of Congress for 2002:

(1) Alien (1979)
(2) All My Babies (1953)
(3) The Bad and the Beautiful (1952)
(4) Beauty and the Beast (1991)
(5) The Black Stallion (1979)
(6) Boyz N the Hood (1991)

(7) Theodore Case Sound Test: Gus Visser and his Singing Duck (1925)
(8) The Endless Summer (1966)
(9) From Here to Eternity (1953)
(10) From Stump to Ship (1930)
(11) Fuji (1974)
(12) In the Heat of the Night (1967)
(13) Lady Windermere's Fan (1925)
(14) Melody Ranch (1940)
(15) The Pearl (1948)
(16) Punch Drunks (1934)
(17) Sabrina (1954)
(18) Star Theatre (1901)
(19) Stranger Than Paradise (1984)
(20) This is Cinerama (1952)
(21) This is Spinal Tap (1984)
(22) Through Navajo Eyes (series) (1966)
(23) Why Man Creates (1968)
(24) Wild and Wooly (1917)
(25) Wild River (1960)

(b) In keeping with section 106(a) of the Act, 2 U.S.C. 179(p), the Librarian shall endeavor to obtain an archival quality copy for each of these twenty-five films for the National Film Registry Collection of the Library of Congress.

**James H. Billington,**

*The Librarian of Congress.*

[FR Doc. 03–5958 Filed 3–12–03; 8:45 am]

BILLING CODE 1410–34–P

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 17

**RIN 2900–AJ34**

### Provision of Drugs and Medicines to Certain Veterans in State Homes

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** This document affirms amendments to the Department of Veterans Affairs ''Medical'' regulations concerning the provision of drugs and medicines prescribed by non-VA physicians for certain veterans who are permanently housebound or in need of regular aid and attendance. The amendments allow prescriptions to be filled by non-VA pharmacies in state homes under contract with VA for filling prescriptions for patients in state homes. This is consistent with VA's special relationship with state homes. It eliminates duplication of services and helps to improve timeliness for filling prescriptions in state homes.

**DATES:** *Effective Date:* March 13, 2003.

**FOR FURTHER INFORMATION CONTACT:** Jeff Ramirez, Pharmacy Service (119), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 273–8428. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** The VA ''Medical'' regulations are set forth at 38 CFR Part 17.96. The interim final rule amending these regulations was published in the **Federal Register** on July 14, 1998 at 63 FR 37779.

We provided a 60-day comment period that ended September 14, 1998. We received two comments. One commenter expressed support. The other commenter stated that the eligibility criteria should be liberalized to only require that a veteran be ''eligible for compensation or pension benefits.'' However, there is a statutory requirement that a veteran be in receipt of benefits to qualify for the provision of drugs and medicines. 38 U.S.C. 1712(d). No change is made based upon this comment. This commenter also states that it would be more efficient and cost-effective to authorize state homes to purchase prescription drugs and medicines from local VA suppliers. No change in the regulation is made based upon this comment. What the commenter suggests is what is happening in those state homes that have contracts with VA to furnish drugs off the Federal Supply Schedule at the same price that VA pays. If other state homes want access to the Federal Supply Schedule, they may achieve that access by contracting with VA. Based on the rationale set forth in the interim final rule and in this document we now affirm as a final rule the changes made by the interim final rule.

#### Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

#### Administrative Procedure Act

This document without any changes affirms amendments made by an interim final rule that is already in effect. Accordingly, we have concluded under 5 U.S.C. 553 that there is good cause for dispensing with a delayed effective date based on the conclusion that such procedure is impracticable, unnecessary, and contrary to the public interest.

#### Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

#### Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule will have only a miniscule effect on any small entity. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of §§ 603 and 604.

#### Catalog of Federal Domestic Assistance Program Number

The Catalog of Federal Domestic Assistance program number for this document is 64.012.

#### List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: March 3, 2003.

**Anthony J. Principi,**

*Secretary of Veterans Affairs.*

### PART 17—MEDICAL

Accordingly, the interim final rule amending 38 CFR part 17 which was published at 63 FR 37779 on July 14, 1998, is adopted as a final rule without change.

[FR Doc. 03–6099 Filed 3–12–03; 8:45 am]

BILLING CODE 8320–01–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[FL–82–200309(w); FRL–7466–4]**

### Approval and Promulgation of Implementation Plans for Florida: Withdrawal of Direct Final Rule

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Withdrawal of direct final rule.

**SUMMARY:** Due to adverse comment, EPA is withdrawing the direct final rule published January 27, 2003, (see 68 FR 3817) approving revisions to the Florida State Implementation Plan. The purpose

of the revision to rule 62–212.400 was to correct discrepancies between State and Federal rule language on exemptions from Prevention of Significant Deterioration and to include additional provisions. EPA stated in the direct final rule that if EPA received adverse comment by February 26, 2003, the rule would be withdrawn and not take effect. EPA subsequently received adverse comment. EPA will address the comment in a subsequent final action based upon the proposed action published on January 27, 2003 (see 68 FR 3847). EPA will not institute a second comment period on this action.

**DATES:** The direct final rule is withdrawn as of March 13, 2003.

**FOR FURTHER INFORMATION CONTACT:** Heidi LeSane, Air Planning Branch, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Phone number: 404/562–9035; E-mail: *lesane.heidi@epa.gov.*

**List of Subjects in 40 CFR Part 52**

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: March 6, 2003.

**J.I. Palmer, Jr.,**

*Regional Administrator, Region 4.*

[FR Doc. 03–6111 Filed 3–12–03; 8:45 am]

**BILLING CODE 6560–50–P**

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 62

**[Region II Docket No. NY58–253a, FRL–7464–8]**

## Approval and Promulgation of State Plans for Designated Facilities; New York

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking direct final action to approve the State plan submitted by New York State to implement and enforce the Emission Guidelines (EG) for existing small Municipal Waste Combustion (MWC) Units. New York's plan establishes emission limits and other requirements for the purpose of reducing toxic air emissions from small MWC units throughout the State. New York submitted its plan to fulfill the requirements of sections 111(d) and 129 of the Clean Air Act.

**DATES:** This direct final rule is effective on May 12, 2003 without further notice, unless EPA receives adverse comment by April 14, 2003.

If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

**ADDRESSES:** All comments should be addressed to: Raymond Werner, Chief, Air Programs Branch, Environmental Protection Agency, Region II Office, 290 Broadway, New York, New York 10007–1866.

Copies of the state submittal is available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region II Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866.

New York State Department of Environmental Conservation, Division of Air Resources, 625 Broadway, 2nd Floor, Albany, New York 12233.

**FOR FURTHER INFORMATION CONTACT:** Anthony (Ted) Gardella, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4249.

**SUPPLEMENTARY INFORMATION:** The following table of contents describes the format for the **SUPPLEMENTARY INFORMATION** section:

I. EPA Action
- A. What action is EPA taking today?
- B. Why is EPA taking this action?
- C. Who is affected by New York's State plan?
- D. How does this approval affect sources located in Indian Nation Land?
- E. How does this approval relate to the Federal plan?

II. Background
- A. What is a State plan?
- B. What is a small MWC State plan?
- C. Why is EPA requiring New York to submit a small MWC State plan?
- D. What are the requirements for a small MWC State plan?

III. New York's State Plan
- A. What is contained in the New York State plan?
- B. What approval criteria did we use to evaluate New York's State plan?

IV. EPA's Rulemaking Action

V. Statutory and Executive Order Reviews

## I. EPA Action

### *A. What Action Is EPA Taking Today?*

EPA is approving New York's State plan, submitted on October 22, 2002, for the control of air emissions from existing small Municipal Waste Combustion (MWC) units throughout the State, except for those small MWCs located on Indian Nation land. New York submitted its plan to fulfill the requirements of section 111(d) and 129 of the Clean Air Act (CAA). The State plan adopts and implements the Emission Guidelines (EG) applicable to existing small MWCs, and establishes emission limits and other requirements for units constructed on or before August 30, 1999. This approval, once effective, will make the New York small MWC rules included in the State plan federally enforceable.

### *B. Why Is EPA Taking This Action?*

EPA has evaluated New York's small MWC State plan for consistency with the CAA, EPA guidelines and policy. EPA has determined that New York's State plan meets all requirements and therefore, EPA is approving New York's State plan to implement and enforce the EG applicable to existing small MWCs.

### *C. Who Is Affected by New York's State Plan?*

New York's State plan regulates all the units designated by the EG for existing small MWCs which commenced construction on or before August 30, 1999 and which have the capacity to combust at least 35 tons per day of municipal solid waste or refuse-derived fuel but no more than 250 tons per day of municipal solid waste or refuse-derived fuel. If the owner or operator of a small MWC made changes after June 6, 2001, that meet the definition of modification or reconstruction for subpart AAAA (New Source Performance Standards for New Small Municipal Waste Combustion Units) of 40 CFR part 60, the small MWC unit becomes subject to subpart AAAA and the State plan no longer applies to that unit.

### *D. How Does This Approval Affect Sources Located in Indian Nation Land?*

New York's State plan does not cover units located in Indian Nation Land. Therefore, any units located in Indian Nation Land will be subject to the Federal plan, subpart JJJ of 40 CFR part 62, promulgated on January 31, 2003 (see 68 FR 5144).

### *E. How Does This Approval Relate to the Federal Plan?*

The Federal plan is applicable to small MWC units located in Indian Nation Land and units throughout New York for which there is no approved State plan. Therefore, until this approval action becomes effective, small MWC units within New York State's jurisdiction are subject to the Federal plan. Upon approval of New York's

State plan, small MWC units within the State of New York's jurisdiction will be subject to New York's State plan as of the effective date of this action and the Federal plan will no longer apply.

## II. Background

### *A. What Is a State Plan?*

Section 111 of the CAA, ''Standards of Performance for New Stationary Sources,'' authorizes EPA to set air emissions standards for certain categories of sources. These standards are called New Source Performance Standards (NSPS). When a NSPS is promulgated for new sources, section 111(d) also requires that EPA publish an EG applicable to the control of the same pollutant from existing (or designated) facilities. States with designated facilities must then develop a State plan to adopt the EG into the State's body of regulations. States must also include in their State plan other requirements, such as inventories, legal authority, and public participation documentation, to demonstrate their ability to enforce the State plans.

### *B. What Is a Small MWC State Plan?*

A small MWC State plan is a State plan, as described above, that controls air pollutant emissions from existing small incinerators with a combustion design capacity of 35 to 250 tons per day of municipal solid waste or refuse derived fuel that commenced construction on or before August 30, 1999.

### *C. Why Is EPA Requiring New York To Submit a Small MWC State Plan?*

When EPA developed the NSPS for small MWCs, we simultaneously developed the EG to control air emissions from existing small MWCs (see 62 FR 76378, December 6, 2000). Under section 129 of the CAA, the EG is not federally enforceable; therefore, section 129 of the CAA also requires states to submit to EPA for approval State plans that implement and enforce the EG. These State plans must be at least as protective as the EG, and they become federally enforceable upon approval by EPA.

The procedures for adopting and submitting State plans are located in 40 CFR part 60, subpart B. If a state fails to have an approvable plan in place by December 6, 2001, the EPA is required to promulgate a Federal plan to establish requirements for those sources not under an EPA-approved State plan. Even though EPA promulgated the Federal plan on January 31, 2003, New York's State plan is approvable since it was deemed at least as protective as the standards set in the EG. New York has developed and submitted a State plan, as required by section 111(d) of the CAA, to gain Federal approval to implement and enforce the small MWC EG.

### *D. What Are the Requirements for a Small MWC State Plan?*

A section 111(d) State plan submittal must meet the requirements of 40 CFR part 60, subpart B, §§ 60.23 through 60.26, and 40 CFR part 60, subpart BBBB (see 62 FR 76378, December 6, 2000). Subpart B contains the procedures for the adoption and submittal of State plans. This subpart addresses public participation, legal authority, emission standards and other emission limitations, compliance schedules, emission inventories, source surveillance, and compliance assurance and enforcement requirements.

EPA promulgated the EG as 40 CFR part 60, subpart BBBB on December 6, 2000. Subpart BBBB contains the technical requirements for existing small MWCs and applies to units that commenced construction on or before August 30, 1999. A state will generally address the small MWC technical requirements by adopting by reference subpart BBBB. The section 111(d) state plan is required to be submitted within one year of the EG promulgation date, *i.e.* by December 6, 2001. Prior to submittal to EPA, the State must make available to the public the State plan and provide opportunity for public comment.

## III. New York's State Plan

### *A. What Is Contained in the New York State Plan?*

On October 22, 2002, the New York State Department of Environmental Conservation (NYSDEC) submitted its section 111(d) State plan for implementing EPA's EG for existing small MWC units located in New York State.

New York has adopted by reference the requirements of the EG in Part 200 of Title 6 of the New York Code of Rules and Regulations (6NYCRR) of the State of New York, entitled ''General Provisions'' and in Subpart 219–1 of 6NYCRR entitled ''Incineration-General Provisions'' and Subpart 219–8 of 6NYCRR entitled ''Emission Guidelines and Compliance Times for Small Municipal Waste Combustion Units Constructed on or before August 30, 1999.'' These amended regulations became effective on October 18, 2002. By incorporating the EG by reference into Part 200, NYSDEC has the authority to include them as applicable within Subpart 219–8, which addresses the applicability of the various Part 219 (New York's incineration rules) requirements. Part 219 now includes the new requirements incorporated from the EG, as well as the necessary compliance schedules and necessary definition changes required for the transformation of emission guidelines into a State plan. As a result, the Part 219 requirements are enforceable by New York and become federally enforceable once the State plan is approved by EPA.

New York's State plan contains the following:

(1) A demonstration of the State's legal authority to implement the section 111(d) State plan;

(2) State rules adopted into 6NYCRR Parts 200 and 219 as the mechanism for implementing and enforcing the State plan;

(3) An inventory of three known small MWC facilities, including eight small MWC units, along with an inventory of their air pollutant emissions;

(4) Emission limits that are as protective as the EG;

(5) Enforceable compliance schedules incorporated into Part 219, New York's incineration rule. For Class I Units, compliance dates vary from three years from the effective date of EPA's approval of New York's State plan to not later than December 6, 2005, whichever is earlier. For Class II Units, compliance dates vary from one year from the effective date of EPA's approval of New York's State plan to not later than December 6, 2005, whichever is earlier.

(6) Testing, monitoring, reporting and recordkeeping requirements for the designated facilities;

(7) Records of the public hearing on the State plan; and,

(8) Provisions for annual state progress reports to EPA on implementation of the State plan.

### *B. What Approval Criteria Did We Use To Evaluate New York's State Plan?*

EPA reviewed New York's State plan for approval against the following criteria: 40 CFR 60.23 through 60.26 , ''Subpart B—Adoption and Submittal of State Plans for Designated Facilities;'' and 40 CFR 60.1600 through 60.1940, ''Subpart BBBB—Emission Guidelines and Compliance Times for Small Municipal Waste Combustion Units Constructed on or Before August 30, 1999.''

## IV. EPA's Rulemaking Action

The EPA has determined that New York's State plan meets all the applicable approval criteria and, therefore, EPA is approving, through direct final rulemaking action, New

York State's sections 111(d) and 129 State plan for small MWCs.

The EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective May 12, 2003 without further notice unless the Agency receives adverse comments by April 14, 2003.

If the EPA receives adverse comments, then EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

## V. Statutory and Executive Order Reviews

*Executive Order 12866: Regulatory Planning and Review*

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled ''Regulatory Planning and Review.''

*Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This rule will not have a significant impact on a substantial number of small entities. Therefore, because the Federal approval does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

*Unfunded Mandates Reform Act*

Under sections 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of $100 million or more to either state, commonwealth, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under state or local law, and imposes no new requirements. Accordingly, no additional costs to state, commonwealth, local, or tribal governments, or to the private sector, result from this action.

*Executive Order 13132: Federalism*

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations 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.''

Under section 6(b) of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by state and local governments, or EPA consults with state and local officials early in the process of developing the proposed regulation. Under section 6(c) of Executive Order 13132, EPA may not issue a regulation that has federalism implications and that preempts state law, unless the Agency consults with state and local officials early in the process of developing the proposed regulation.

New York's State plan applies to all affected sources regardless of whether it has been identified in its plan. Therefore, EPA has concluded that this rulemaking action does not have federalism implications. It will not impose substantial direct compliance costs on state or local governments, nor will it preempt state law. Thus, the requirements of sections 6(b) and 6(c) of the Executive Order do not apply to this rule.

*Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This rule does not have tribal implications. It will not have substantial direct effects on tribal governments, 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, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

*Executive Order 13045: Protection of Children From Environmental Health and Safety Risks*

*Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

*National Technology Transfer Advancement Act*

Section 12 of the National Technology Transfer Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

*Congressional Review Act*

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2). This rule will be effective May 12, 2003 unless EPA receives material adverse written comments by April 14, 2003.

*Petitions for Judicial Review*

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 12, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 62**

Environmental protection, Air pollution control, Intergovernmental relations, Lead, Reporting and recordkeeping requirements.

Dated: March 3, 2003.

**Jane M. Kenny,**

*Regional Administrator, Region 2.*

Part 62, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

## PART 62—[AMENDED]

1. The authority citation for part 62 continues to read as follows:

**Authority:** 42 U.S.C. 7401–7671q.

## Subpart HH—New York

2. Part 62 is amended by adding new § 62.8107 and an undesignated heading to subpart HH to read as follows:

Air Emissions From Existing Small Municipal Waste Combustion Units With The Capacity To Combust At Least 35 Tons Per Day But No More Than 250 Tons Per Day Of Municipal Solid Waste Or Refuse Derived Fuel and Constructed on or Before August 30, 1999.

### § 62.8107 Identification of plan.

(a) On October 22, 2002, the New York State Department of Environmental Conservation submitted to the Environmental Protection Agency ''Section 111(d)/129 State Plan for Implementation of Municipal Waste Combustor Emission Guidelines [Title 40 CFR Part 60, Subparts B and BBBB]''

(b) Identification of sources: The plan applies to all existing Small Municipal Waste Combustion Units with the capacity to combust at least 35 tons per day but no more than 250 tons per day of municipal solid waste or refuse derived fuel and constructed on or before August 30, 1999.

(c) The effective date for the portion of the plan applicable to existing municipal waste combustor units is May 12, 2003.

[FR Doc. 03–5908 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 271

**[FRL–7465–8]**

## Virginia: Final Authorization of State Hazardous Waste Management Program Revision

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Immediate final rule.

**SUMMARY:** Virginia has applied to EPA for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has determined that these changes satisfy all requirements needed to qualify for final authorization and is authorizing Virginia's changes through this immediate final action. EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize Virginia's changes to its hazardous waste program will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal Register** will serve as a proposal to authorize the changes.

**DATES:** This final authorization will become effective on May 12, 2003, unless EPA receives adverse written comment by April 14, 2003. If EPA receives any such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect as scheduled.

**ADDRESSES:** Send written comments to Joanne Cassidy, Mailcode 3WC21, RCRA State Programs Branch, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–3381. You may inspect and copy Virginia's application from 8:15 a.m. to 4:30 p.m., at the following addresses: Virginia Department of Environmental Quality, Division of Waste Program Coordination, 629 East Main Street, Richmond, VA 23219, Phone number: (804) 698–4213, attn: Robert Wickline, and Virginia Department of Environmental Quality, West Central Regional Office, 3019 Peters Creek Road, Roanoke, VA 24015, Phone number: (540) 562–6872, attn: Aziz Farahmand, and EPA Region III, Library, 2nd Floor, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–5254.

**FOR FURTHER INFORMATION CONTACT:** Joanne Cassidy, Mailcode 3WC21, RCRA State Programs Branch, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–3381.

**SUPPLEMENTARY INFORMATION:**

### A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program

that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

### B. What Decisions Has EPA Made in This Rule?

EPA concludes that Virginia's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Virginia final authorization to operate its hazardous waste program with the changes described in its application for program revisions. Virginia has responsibility for permitting treatment, storage, and disposal facilities (TSDFs) within its borders and for carrying out the aspects of the RCRA program described in its application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, EPA will implement those HSWA requirements and prohibitions in Virginia, including issuing HSWA permits, until the State is granted authorization to do so.

### C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Virginia subject to RCRA will now have to comply with the authorized Virginia regulatory revisions instead of the equivalent revised Federal requirements in order to comply with RCRA. Virginia has enforcement responsibilities under its state hazardous waste program for violations of its program, but EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

- Perform inspections, and require monitoring, tests, analyses or reports;
- Enforce RCRA requirements and suspend or revoke permits; and
- Take enforcement actions regardless of whether Virginia has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations for which Virginia is being authorized by today's action are already effective and are not changed by today's action.

### D. Why Wasn't There a Proposed Rule Before Today's Rule?

EPA did not publish a proposal before today's rule because we view this as a routine program change and do not expect comments that oppose this approval. We are providing an opportunity for public comment now. In addition to this rule, in the proposed rules section of today's **Federal Register** we are publishing a separate document that proposes to authorize Virginia's program changes. If EPA receives comments which oppose this authorization that document will serve as a proposal to authorize such changes.

### E. What Happens if EPA Receives Comments That Oppose This Action?

If EPA receives comments that oppose this authorization, we will withdraw this rule by publishing a document in the **Federal Register** before the rule becomes effective. EPA will base any further decision on the authorization of Virginia's program changes on the proposal mentioned in the previous paragraph. We will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time.

### F. What Has Virginia Previously Been Authorized for?

Virginia initially received final authorization on December 4, 1984, effective December 18, 1984 (49 FR 47391), to implement the RCRA hazardous waste management program. EPA granted authorization for changes to Virginia's regulatory program on July 31, 2000, effective September 29, 2000 (65 FR 46606).

### G. What Changes Are We Authorizing With Today's Action?

On September 24, 2002, Virginia submitted a final complete program revision application, seeking authorization of its changes in accordance with 40 CFR 271.21. Virginia's revision application includes changes to the Federal hazardous waste program, as published in the **Federal Register** from December 6, 1994 through June 30, 2001, as well as miscellaneous changes to its previously-authorized program. We now make an immediate final decision, subject to receipt of written comments that oppose this action, that Virginia's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Therefore, EPA grants Virginia final authorization for the following program changes:

*1. Program Revision Changes for Federal Rules Published Between December 20, 1994 and June 30, 2001*

Virginia seeks authority to administer the Federal requirements that are listed in Table 1. Except as noted in the Table, Virginia incorporates by reference these Federal provisions, in accordance with the dates specified in Title 9, Virginia Administrative Code (9 VAC 20–60–18). Table 1 lists Virginia's requirements that are being recognized as no less stringent than the analogous Federal requirements. The Virginia Waste Management Act (VWMA), enacted by the 1986 session of the Virginia's General Assembly and recodified in 1988 as Chapter 14, Title 10.1, Code of Virginia, forms the basis of the Virginia program. The regulatory references are to Title 9, Virginia Administrative Code (9 VAC) effective November 21, 2001.

TABLE 1.—VIRGINIA'S ANALOGS TO THE FEDERAL REQUIREMENTS

| Description of Federal requirement (Revision checklists [1]) | Federal Register | Analogous Virginia authority |
|---|---|---|
| **RCRA Cluster V [2]** | | |
| Universal Treatment Standards and Treatment Standards for Organic Characteristic Wastes and Newly Listed Waste (Revision Checklist 137). | 60 *FR* 242, 1/3/95 | Title 9, Virginia Administrative Code (9 VAC) §§ 20–60–18 and 20–60–268 A |
| Testing and Monitoring Activities Amendment I (Revision Checklist 139). | 60 *FR* 3089, 1/13/95 | 9 VAC §§ 20–60–18 and 20–60–260 A |

TABLE 1.—VIRGINIA'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

| Description of Federal requirement (Revision checklists [1]) | Federal Register | Analogous Virginia authority |
|---|---|---|
| Carbamate Production Identification and Listing of Hazardous Waste (Revision Checklist 140). | 60 *FR* 7824, 2/9/95<br>60 *FR* 19165, 4/17/95<br>60 *FR* 25619, 5/12/95 | 9 VAC §§ 20–60–18 and 20–60–261 A |
| Testing and Monitoring Activities Amendment II (Revision Checklist 141). | 60 *FR* 17001, 4/4/95 | 9 VAC §§ 20–60–18 and 20–60–260 A |
| Removal of Legally Obsolete Rules (Revision Checklist 144). | 60 *FR* 33912, 6/29/95 | 9 VAC §§ 20–60–18, 20–60–261 A, 20–60–266 A and 20–60–270 A |
| **RCRA Cluster VI** | | |
| Liquids in Landfills III (Revision Checklist 145) | 60 *FR* 35703, 7/11/95 | 9 VAC §§ 20–60–18, 20–60–264 A and 20–60–265 A |
| RCRA Expanded Public Participation (Revision Checklist 148). | 60 *FR* 63417, 12/11/95 | 9 VAC §§ 20–60–18, 20–60–124 A and 20–60–270 A |
| Recovered Oil Exclusion, Correction (Revision Checklist 150). | 61 *FR* 13103, 3/26/96 | 9 VAC §§ 20–60–18 and 20–60–261 A |
| Land Disposal Restrictions Phase III—Decharacterized Wastewaters, Carbamate Wastes, and Spent Potliners (Revision Checklist 151). | 61 *FR* 15566, 4/8/96<br>61 *FR* 15660, 4/8/96<br>61 *FR* 19117, 4/30/96<br>61 *FR* 33680, 6/28/96<br>61 *FR* 36419, 7/10/96<br>61 *FR* 43924, 8/26/96<br>62 *FR* 7502, 2/19/97 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| **RCRA Cluster VII** | | |
| Conditionally Exempt Small Quantity Generator Disposal Options Under Subtitle D (Revision Checklist 153). | 61 *FR* 34252, 7/1/96 | 9 VAC §§ 20–60–18 and 20–60–261 A |
| Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers (Revision Checklist 154). | 59 *FR* 62896, 12/6/94<br>60 *FR* 26828, 5/19/95<br>60 *FR* 50426, 9/29/95<br>60 *FR* 56952, 11/13/95<br>61 *FR* 4903, 2/9/96<br>61 *FR* 28508, 6/5/96<br>61 *FR* 59932, 11/25/96 | 9 VAC §§ 20–60–18, 20–60–260 A, 20–60–261 A, 20–60–262 A, 20–60–264 A, 20–60–265 A and 20–60–270 A |
| Land Disposal Restrictions Phase III—Emergency Extension of the K088 Capacity Variance (Revision Checklist 155). | 62 *FR* 1992, 1/14/97 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Military Munitions Rule (Revision Checklist 156) | 62 *FR* 6622, 2/12/97 | 9 VAC §§ 20–60–18, 20–60–260 A, 20–60–261 A, 20–60–262 A, 20–60–263 A, 20–60–264 A, 20–60–265 A, 20–60–266 A and 20–60–270 A |
| Land Disposal Restrictions—Phase IV (Revision Checklist 157). | 62 *FR* 25998, 5/12/97 | 9 VAC §§ 20–60–18, 20–60–261 A and 20–60–268 A |
| Testing and Monitoring Activities Amendment III (Revision Checklist 158). | 62 *FR* 32452, 6/13/97 | 9 VAC §§ 20–60–18, 20–60–260 A, 20–60–264 A, 20–60–265 A and 20–60–266 A |
| Carbamate Production, Identification and Listing of Hazardous Waste; Land Disposal Restrictions (Conformance With the Carbamate Vacatur) (Revision Checklist 159). | 62 *FR* 32974, 6/17/97 | 9 VAC §§ 20–60–18, 20–60–261 A and 20–60–268 A |
| **RCRA Cluster VIII** | | |
| Land Disposal Restrictions Phase III—Emergency Extension of the K088 National Capacity Variance (Revision Checklist 160). | 62 *FR* 37694, 7/14/97 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Second Emergency Revision of the Land Disposal Restrictions (LDR) Treatment Standards for Listed Hazardous Wastes From Carbamate Production (Revision Checklist 161). | 62 *FR* 45568, 8/28/97 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Clarification of Standards for Hazardous Waste Land Disposal Restriction Treatment Variances (Revision Checklist 162). | 62 *FR* 64504, 12/5/97 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Organic Air Emission Standards for Tanks, Surface Impoundments, and Containers (Revision Checklist 163). | 62 *FR* 64636, 12/8/97 | 9 VAC §§ 20–60–18, 20–60–264 A, 20–60–265 A and 20–60–270 A |
| Kraft Mill Stream Stripper Condensate Exclusion (Revision Checklist 164). | 63 *FR* 18504, 4/15/98 | 9 VAC §§ 20–60–18 and 20–60–261 A |
| LDR Phase IV—Treatment Standards for Metal Wastes and Mineral Processing Wastes (Revision Checklist 167A). | 63 *FR* 28556, 5/26/98 | 9 VAC §§ 20–60–18 and 20–60–268 A |

TABLE 1.—VIRGINIA'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

| Description of Federal requirement (Revision checklists [1]) | Federal Register | Analogous Virginia authority |
|---|---|---|
| LDR Phase IV—Hazardous Soils Treatment Standards and Exclusions (Revision Checklist 167B). | 63 *FR* 28556, 5/26/98 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| 167C—LDR Phase IV—Corrections (Revision Checklist 167C). | 63 *FR* 28556, 5/26/98<br>63 *FR* 31266, 6/8/98 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Mineral Processing Secondary Materials Exclusion (Revision Checklist 167D). | 63 *FR* 28556, 5/26/98 | 9 VAC § 20–60–18 and 20–60–261 A |
| Bevill Exclusion Revisions and Clarification (Revision Checklist 167E). | 63 *FR* 28556, 5/26/98 | 9 VAC §§ 20–60–18 and 20–60–261 A |
| Hazardous Waste Combustors Revised Standards (Revision Checklist 168). | 63 *FR* 33782, 6/19/98 | 9 VAC § 20–60–18, 20–60–261 A and 20–60–270 A |
| **RCRA Cluster IX** | | |
| Petroleum Refining Process Wastes (Revision Checklist 169). | 63 *FR* 42110, 8/6/98<br>63 *FR* 54356, 10/9/98 | 9 VAC §§ 20–60–18, 20–60–261 A, 20–60–266 A and 20–60–268 A |
| Land Disposal Restrictions Phase IV—Zinc Micronutrient Fertilizers, Administrative Stay (Revision Checklist 170). | 63 *FR* 46332, 8/31/98 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Emergency Revision of the Land Disposal Restrictions (LDR) Treatment Standards for Listed Hazardous Wastes from Carbamate Production (Revision Checklist 171). | 63 *FR* 47410, 9/4/98 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Land Disposal Restrictions Phase IV—Extension of Compliance Date for Characteristic Slags (Revision Checklist 172). | 63 *FR* 48124, 9/9/98 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Land Disposal Restrictions; Treatment Standards for Spent Potliners from Primary Aluminum Reduction (K088); Final Rule (Revision Checklist 173). | 63 *FR* 51254, 9/24/98 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Post-Closure Requirements and Closure Process (Revision Checklist 174). | 63 *FR* 56710, 10/22/98 | 9 VAC §§ 20–60–18, 20–60–264 A, 20–60–265 A and 20–60–270 A |
| HWIR-Media (Revision Checklist 175) | 63 *FR* 65874, 11/30/98 | 9 VAC §§ 20–60–18, 20–60–260 A, 20–60–261 A, 20–60–264 A, 20–60–265 A, 20–60–268 A, 20–60–270 A and 20–60–270 B 14<br>Note: At 9 VAC 20–60–270 B 14, Virginia clarifies that the EPA appeal rights and procedures related to remedial action plan (RAP), as specified in 40 CFR 270.155, are not incorporated into the Virginia regulations. Appeals of actions related to RAPs are governed by Virginia's Administrative Process Act, Title 2.2, Chapter 40, §§ 2.2–4000 through 2.2–4033, Code of Virginia. |
| Universal Waste Rule—Technical Amendments (Revision Checklist 176). | 63 *FR* 71225, 12/24/98 | 9 VAC § 20–60–18, 20–60–266 A and 20–60–273 A |
| Organic Air Emission Standards: Clarification and Technical Amendments (Revision Checklist 177). | 64 *FR* 3382, 1/21/99 | 9 VAC §§ 20–60–18, 20–60–262 A, 20–60–264 A and 20–60–265 A |
| Petroleum Refining Process Wastes—Leachate Exemption (Revision Checklist 178). | 64 *FR* 6806, 2/11/99 | 9 VAC §§ 20–60–18 and 20–60–261 A |
| Land Disposal Restrictions Phase IV—Technical Corrections and Clarifications to Treatment Standards (Revision Checklist 179). | 64 *FR* 25408, 5/11/99 | 9 VAC §§ 20–60–18, 20–60–261 A, 20–60–262 A and 20–60–268 A |
| Test Procedures for the Analysis of Oil and Grease and Non-Polar Material (Revision Checklist 180). | 64 *FR* 26315, 5/14/99 | 9 VAC §§ 20–60–18 and 20–60–260 A |
| **RCRA Cluster X** | | |
| Universal Waste Rule: Specific Provisions for Hazardous Waste Lamps (Revision Checklist 181). | 64 *FR* 36466, 7/6/99 | 9 VAC §§ 20–60–18, 20–60–260 A, 20–60–261 A, 20–60–264 A, 20–60–265 A, 20–60–268 A, 20–60–270 A, 20–60–273 A, and 20–60–273 B.3.a |
| Hazardous Air Pollutant Standards for Combustors, Miscellaneous Units, and Secondary Lead Smelters; Clarification of BIF Requirements; Technical Correction to Fast-track Rule (Revision Checklist 182). | 64 *FR* 52828, 9/30/99<br>64 *FR* 63209, 11/19/99 | 9 VAC §§ 20–60–18, 20–60–260 A, 20–60–261 A, 20–60–264 A, 20–60–265 A, 20–60–266 A and 20–60–270 A |
| Land Disposal Restrictions Phase IV—Technical Corrections (Revision Checklist 183). | 64 *FR* 56469, 10/20/99 | 9 VAC §§ 20–60–18, 20–60–261 A, 20–60–262 A and 20–60–268 A |
| Accumulation Time for Waste Water Treatment Sludges (Revision Checklist 184). | 65 *FR* 12378, 3/8/00 | 9 VAC §§ 20–60–18 and 20–60–262 A |
| Vacatur of Organobromine Production Waste Listings (Revision Checklist 185). | 65 *FR* 14472, 3/17/00 | 9 VAC §§ 20–60–18, 20–60–261 A and 20–60–268 A |

TABLE 1.—VIRGINIA'S ANALOGS TO THE FEDERAL REQUIREMENTS—Continued

| Description of Federal requirement (Revision checklists [1]) | Federal Register | Analogous Virginia authority |
|---|---|---|
| Petroleum Refining Process Wastes—Clarification (Revision Checklist 187). | 65 *FR* 36365, 6/8/00 | 9 VAC §§ 20–60–18, 20–60–261 A and 20–60–268 A |
| **RCRA Cluster XI** | | |
| Hazardous Air Pollutant Standards; Technical corrections (Revision Checklist 188). | 65 *FR* 42292, 7/10/00<br>66 *FR* 24270, 5/14/01 | 9 VAC §§ 20–60–18, 20–60–261 A, 20–60–264 A and 20–60–270 A |
| Chlorinated Aliphatics Listing and LDRs for Newly Identified Wastes (Revision Checklist 189). | 65 *FR* 67068, 11/8/00 | 9 VAC §§ 20–60–18, 20–60–261 A and 20–60–268 A |
| Land Disposal Restrictions Phase IV—Deferral for PCBs in Soil (Revision Checklist 190). | 65 *FR* 81373, 12/26/00 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Mixed Waste Rule (Revision Checklist 191) | 66 *FR* 27218, 5/16/01 | 9 VAC §§ 20–60–18 and 20–60–266 A |
| Mixture and Derived-From Rules Revisions (Revision Checklist 192A). | 66 *FR* 27266, 5/16/01 | 9 VAC §§ 20–60–18 and 20–60–261 A |
| Land Disposal Restrictions Correction (Revision Checklist 192B). | 66 *FR* 27266, 5/16/01 | 9 VAC §§ 20–60–18 and 20–60–268 A |
| Change of Official EPA Mailing Address (Revision Checklist 193). | 66 *FR* 34374, 6/28/01 | 9 VAC §§ 20–60–18 and 20–60–260 A |
| **PROJECT XL** | | |
| Project XL Site-Specific Rulemaking for Merck & Co., Inc., Stonewall Plant, Elkton, VA. | 62 *FR* 59621, 10/8/97 | 9 VAC §§ 20–60–18, 20–60–264 and 20–60–265 A |

[1] A Revision Checklist is a document that addresses the specific changes made to the Federal regulations by one or more related final rules published in the **Federal Register**. EPA develops these checklists as tools to assist States in developing their authorization applications and in documenting specific State analogs to the Federal regulations. For more information see EPA's RCRA State Authorization Web page at *http://www.epa.gov/epaoswer/hazwaste/state.*

[2] A ''RCRA Cluster'' is a set of Revision Checklists for Federal rules promulgated between July 1 and June 30 of any given year.

*2. Additional Requirements for Universal Waste Handlers of Hazardous Waste Lamps*

In the preamble of the July 6, 1999 Universal Waste Rule for hazardous waste lamps (64 FR 36466 *et seq.*), EPA stated that the Agency will consider authorization of State programs that include provisions for controlling the treatment or crushing of universal waste lamps, if the State program can be shown to be equivalent to the Federal prohibition (see p. 36478, column 1). Virginia has adopted and is seeking authorization for requirements at 9 VAC sections 20–60–273.B.3.b and 20–60–273.B.3.c which allow universal waste handlers to crush universal waste lamps at the site of generation in order to reduce their volume before transportation. Virginia's lamp crushing regulations include technical requirements for controlling emissions of hazardous constituents to levels established by the Federal Occupational Safety and Health Administration (OSHA), and specific operational recordkeeping requirements. EPA has reviewed Virginia's universal waste lamp regulations and has determined that the State's requirements are at least as protective as, and therefore equivalent to, the Federal prohibition on the treatment of universal waste lamps. Therefore, EPA grants Virginia final authorization for its universal waste lamp regulations, which provide for lamp crushing.

*3. Miscellaneous Changes*

In addition to adopting Federal program revisions by means of updating the effective date of the incorporation by reference of the Code of Federal Regulations to July 1, 2001, Virginia has made various additional regulatory revisions since its first program revision application. Virginia is seeking authorization for these miscellaneous changes, which became effective March 13, 2002. Among these changes, Virginia reorganized its permit procedures by deleting Part XI (9 VAC 20–60–960 through 9 VAC 20–60–1250) and expanding, as appropriate, the coverage of 9 VAC 20–60–270. Virginia has also adopted the Federal provisions of 40 CFR 260.30 and 260.31 at 9 VAC 20–60–1390 A 2 and 20–60–1390 B respectively, which provide for a petition process for waste variances from classification as a solid waste; and revised various cross-references, principally to conform to the deletion of Part XI. Additional miscellaneous changes are listed following this paragraph. Regulatory citations annotated with an asterisk are deemed to be more stringent than the Federal program. EPA has evaluated the miscellaneous changes described in this section and has determined that they are consistent with and no less stringent than the corresponding Federal regulations.

Title 9, Virginia Administrative Code (9 VAC) §§ 20–60–14 B 3 through B6; 20–60–17 A; 20–60–20 through 20–60–90; 20–60–124 A & B; 20–60–260 B 3 b; 20–60–260 B 8 and B 9; 20–60–261 B 5*, 20–60–262 B 4* and 20–60–262 B 6 and B 7; 20–264 B 5*, 20–60–264 B 7; 20–60–264 B 15 a*; 20–60–264 B 16; 20–60–264 B 17; 20–60–265 B 6*; 20–60–265 B 7; 20–60–265 B 9; 20–60–265 B 18; 20–60–266 B 3; 20–60–270 A; 20–60–270 B 5; 20–60–270 B 6 (except first sentence); 20–60–270 B 7; 20–60–270 B 8; 20–60–270 B 9 introductory paragraph; 20–60–279 B 9 a*; 20–60–270 B 9 b; 20–60–270 B 10*; 20–60–270 B 11*; 20–60–270 B 12*; 20–60–270 B 13; 20–60–273 B 2; 20–60–315 B & C; 20–60–315 H; 20–60–328 A through D; 20–60–1410 A and B; 20–60–1420 B and C; 20–60–1430; and 20–60–1435.

A further discussion of Virginia's miscellaneous regulatory changes is found in the following authorization revision application documents for Virginia: (1) ''Demonstration of Adequate Authority for Virginia Hazardous Waste Management Program Revisions from Program Revision I through June 30, 2001: Program Revision II'' and (2) ''Program Description, Revision II, 2002.''

**H. Where Are the Revised Virginia Rules Different From the Federal Rules?**

Virginia's hazardous waste program contains several provisions which are more stringent than the RCRA program as codified in the July 1, 2001 edition of title 40 of the Code of Federal Regulations (CFR). These more stringent provisions are part of the Federally-authorized program and are, therefore, Federally-enforceable. The specific more stringent provisions are noted in Section G.3.

**I. Who Handles Permits After This Authorization Takes Effect?**

After authorization, Virginia will issue permits for all the provisions for which it is authorized and will administer the permits it issues. EPA will continue to administer any RCRA hazardous waste permits or portions of permits which it issued prior to the effective date of this authorization. Until such time as formal transfer of EPA permit responsibility to Virginia occurs and EPA terminates its permit, EPA and Virginia agree to coordinate the administration of permits in order to maintain consistency. EPA will not issue any additional new permits or new portions of permits for the provisions listed in Section G after the effective date of this authorization. EPA will continue to implement and issue permits for HSWA requirements for which Virginia is not yet authorized.

**J. How Does Today's Action Affect Indian Country (18 U.S.C. 115) in Virginia?**

Virginia is not seeking authority to operate its program on Indian lands, since there are no Federally-recognized Indian Lands in Virginia.

**K. What Is Codification and Is EPA Codifying Virginia's Hazardous Waste Program as Authorized in This Rule?**

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. EPA does this by referencing the authorized State rules in 40 CFR part 272. EPA reserves the amendment of 40 CFR part 272, subpart VV, for this authorization of Virginia's program changes until a later date.

**L. Statutory and Executive Order Reviews**

*Statutory and Executive Order Reviews*

This rule only authorizes hazardous waste requirements pursuant to RCRA 3006 and imposes no requirements other than those imposed by State law (*see* **SUPPLEMENTARY INFORMATION**, Section A. Why are Revisions to State Programs Necessary?). Therefore, this rule complies with applicable executive orders and statutory provisions as follows.

*1. Executive Order 12866: Regulatory Planning Review*

The Office of Management and Budget has exempted this rule from its review under Executive Order (EO) 12866.

*2. Paperwork Reduction Act*

This rule does not impose an information collection burden under the Paperwork Reduction Act.

*3. Regulatory Flexibility Act*

After considering the economic impacts of today's rule on small entities under the Regulatory Flexibility Act, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

*4. Unfunded Mandates Reform Act*

Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act.

*5. Executive Order 13132: Federalism*

EO 13132 does not apply to this rule because it will not have federalism implications (*i.e.*, 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).

*6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

EO 13175 does not apply to this rule because it will not have tribal implications (*i.e.*, substantial direct effects 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).

*7. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks*

This rule is not subject to EO 13045 because it is not economically significant and it is not based on health or safety risks.

*8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This rule is not subject to EO 13211 because it is not a significant regulatory action as defined in EO 12866.

*9. National Technology Transfer Advancement Act*

EPA approves State programs as long as they meet criteria required by RCRA, so it would be inconsistent with applicable law for EPA, in its review of a State program, to require the use of any particular voluntary consensus standard in place of another standard that meets the requirements of RCRA. Thus, Section 12(d) of the National Technology Transfer and Advance Act does not apply to this rule.

*10. Congressional Review Act*

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 *et seq.*) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective on May 12, 2003.

**List of Subjects in 40 CFR Part 271**

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

**Authority:** This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: March 5, 2003.

**Thomas Voltaggio,**

*Acting Regional Administrator, EPA Region III.*

[FR Doc. 03–6109 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Parts 2 and 25

**[ET Docket No. 00–258 and IB Docket No. 99–81; FCC 03–16]**

## Advanced Wireless Service

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document reallocate portions of the frequency band currently used by the Mobile-Satellite Service (MSS) to provide additional spectrum for Fixed and Mobile Services, and deny Cellular Telecommunications and Internet Association's petition for reconsideration. This action furthers the Commission's efforts to identify and reallocate spectrum that can be used to promote the development and deployment of advanced wireless services, including those commonly associated with ''3G'' wireless applications.

**DATES:** Effective April 14, 2003.

**FOR FURTHER INFORMATION CONTACT:** Jamison Prime, Office of Engineering and Technology, (202) 418–7474.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Third Report and Order and Memorandum Opinion and Order,* ET Docket No. 00–258 and IB Docket No. 99–81, FCC 03–16, adopted January 29, 2003, and released February 10, 2003. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365.

## Summary of the Third Report and Order and Memorandum Opinion and Order

1. In the *Third Report and Order,* the Commission reallocated 30 megahertz of spectrum in the 2 GHz MSS band for Fixed and Mobile services on a primary basis and preserved the remaining 40 megahertz of spectrum for Mobile-Satellite Service (MSS) at this time. The Commission reallocated 15 megahertz from the MSS uplink band, specifically the 1990–2000 MHz and 2020–2025 MHz band segments, and 15 megahertz from the MSS downlink band, specifically the 2165–2180 MHz band segment. We modified the Table of Allocations to provide for Fixed and Mobile services in these bands on a co-primary basis. In addition, we also modified footnotes NG 156 and NG 168 of the U.S. Table of Frequency Allocations, concerning Fixed and Mobile service status in bands shared with MSS, to reflect the revised MSS bands. The Commission created two new non-Federal Government footnotes that make incumbent BAS and cable television relay service operations that are secondary to MSS also secondary to new Fixed and Mobile services after prescribed cut-off dates. Finally, we conclude that some abandoned 2 GHz spectrum recently recaptured as a result of the initial MSS milestone review will be reassigned to the authorized MSS operators that remain when we complete the initial milestone review.

2. The 30 megahertz of spectrum that was reallocated from MSS comes from two sources: 14 megahertz of spectrum that was not assigned to any of the MSS licensees and 16 megahertz of spectrum (of the 21 megahertz) that had been abandoned at the time the *Third R&O* was adopted, as a result of MSS licensees not meeting initial milestones. The International Bureau has cancelled three MSS authorizations, thereby recapturing 21 megahertz of spectrum. Sixteen megahertz of this recaptured spectrum, as well as the 14 megahertz of unassigned spectrum, will be reallocated immediately for Fixed and Mobile services. Relying on unassigned and abandoned spectrum as the basis for the reallocation is least disruptive to the MSS licensees. Further, the initial MSS milestone review, which is not yet completed, has already made available an additional 5 megahertz of abandoned spectrum that we are not reallocating for new services. We note that the MSS entities have asserted the need for access to more than 3.5 megahertz of spectrum in each band for their Selected Assignments. We thus conclude that the public interest would be served by redistributing abandoned 2 GHz spectrum recently recaptured as a result of the initial MSS milestone review, above the 16 megahertz being reallocated, to the authorized MSS operators that remain when we complete the initial milestone review. Thus, it is possible that more than 5 megahertz of abandoned spectrum may be available for redistribution when the initial MSS milestone review is completed. We further note that the MSS milestone review is an ongoing process that spans several years, and it is possible that not all currently authorized MSS networks will be deployed. As we previously stated in *2 GHz MSS R&O,* 65 FR 59140, Oct. 4, 2000, we have not established nor do we do so here any policy or rule regarding the use of additional abandoned spectrum that may result after future MSS milestone reviews are completed. Instead, we will evaluate whether to redistribute such spectrum or make it available to new entrants after achievement of each of our system implementation milestones.

3. Because we are revising the allocated spectrum for MSS and modifying the amount of spectrum that will constitute a Selected Assignment, we have also modified how Selected Assignments are to be located in the revised MSS bandwidth. In the *2 GHz MSS R&O,* we have determined that the MSS band plan would be divided into equal segments based on the number of licensed MSS systems. This incremental spacing approach allows MSS licensees to identify Selected Assignments working from either the bottom or the top of the band without requiring assignments to be selected in sequential order. In order to maintain this flexibility, the plan for each band will be based on dividing the revised MSS allocation in each band by the number of MSS licensees remaining when we complete the initial MSS milestone review. Thus, MSS licensees will choose Selected Assignments as an integer multiple of this amount from either band edge. We have modified, pursuant to section 316 of the Communications Act, 47 U.S.C. 316, and consistent with our decisions here, the 2 GHz MSS authorizations to increase the amount of spectrum for Selected Assignments, to require that a Selected Assignment be located within the revised MSS allocation, and to require that a Selected Assignment be chosen such that the band edge of the assignment is an integer multiple of the revised value from the band edge. We have also delegated authority to the International Bureau to issue revised authorizations, consistent with the decisions in this *Third Report and Order,* when the initial milestone review is completed. When the authorizations are modified, the MSS entities, can follow current procedures for notifying the Commission of their Selected Assignments and their selections will be put on public notice.

4. In deciding which segments of the MSS spectrum should be reallocated for Fixed and Mobile services, we recognize that the record is split on whether we should reallocate spectrum that overlaps the global MSS allocation, which consists of paired 30 megahertz bands at 1980–2110 MHz and 2170–2200 MHz. The U.S. MSS allocation, which consists of two paired 35 megahertz bands, overlaps 20 megahertz of the international allocation in the lower uplink band (1990–2010 MHz) and all of the 30 megahertz of the international allocation in the upper downlink band (2170–2200 MHz). After careful

consideration of the record, we conclude that, on balance, the benefits to the public of providing additional spectrum for Fixed and Mobile services that overlaps the international 2 GHz MSS band outweigh the impact on MSS. Our decision is to reallocate MSS spectrum in a way that will allow new entrants to take advantage of economies of scale in developing and deploying new services while maintaining sufficient international MSS spectrum.

5. In the 1990–2025 MHz band, we have reallocated from the current MSS allocation a 10 megahertz block at 1990–2000 MHz, which is contiguous with the existing Broadband PCS allocation at 1930–1990 MHz, and a 5 megahertz block at 2020–2025 MHz. Because the 10 megahertz block is contiguous with the Broadband PCS band, this spectrum could provide needed growth spectrum for PCS providers, as well as facilitate new AWS equipment development and deployment. This reallocation will reduce by 10 megahertz the current 20 megahertz available for the international MSS uplink allocation. While we recognize that globally harmonized spectrum is an important resource, we share Cellular Telecommunications and Internet Association's concerns regarding potential interference to existing PCS operations at 1930–1990 MHz. We believe that in this instance, these interference concerns outweigh the benefits of increased global harmonized spectrum. We find that we can accommodate the international needs of 2 GHz MSS licensees in the remaining 10 megahertz (uplink) + 20 megahertz (downlink) of overlapping international spectrum. Not all of the eight authorized MSS networks will be deployed, not all of the proposed MSS networks will be providing global service, and most MSS licensees propose to operate throughout the currently allocated band (2000–2020 MHz). The remaining MSS entities will be able to adapt their frequency use within the U.S. to the remaining allocated spectrum (2000–2020 MHz), and use any spectrum within the international allocation (1980–2010 MHz) outside the U.S. Any newly authorized MSS networks could be built to accommodate the revised MSS allocation, assuming that sharing with incumbent MSS licensees is possible. We conclude that our decision to reduce the amount of globally harmonized MSS spectrum that will be available in the United States is appropriate at this time and consistent with the current spectrum requirements for the global portion of the 2 GHz MSS industry. Despite this action, we remain cognizant and supportive of the benefits of global spectrum harmonization, when appropriate.

6. In the 2165–2200 MHz band, we balanced the MSS and terrestrial services needs by reallocating a 15 megahertz block at 2165–2180 MHz. This reallocation will minimize the impact on MSS, as all of the remaining 20 megahertz domestic allocation will overlap with the current international MSS downlink allocation—and, thus, 30 of the 40 megahertz of remaining MSS spectrum will overlap with the global allocation. We believe that MSS licensees should not be significantly impaired in providing satellite services in this band. We note that, as a result of our previous decision in this docket, 45 megahertz of contiguous spectrum, from 2110–2155 MHz, will be available for AWS. We also have proposed to make the adjacent bands at 2155–2160 and 2160–2165 MHz available for AWS. We note that our decision here to reallocate the adjacent MSS spectrum at 2165–2180 MHz is consistent with the majority of the AWS proponents who favor reallocating MSS spectrum adjacent to the 2110–2165 MHz band. Contiguous spectrum would make it easier to accommodate multiple licensees using larger spectrum blocks throughout this band. Further, a flexible allocation at 2110–2165 MHz would overlap to a large extent the international allocation for a terrestrial component of advanced services at 2110–2170 MHz and thus will promote the timely introduction of new equipment and services in this spectrum.

7. As a consequence of our decision to reallocate the 1990–2000/2020–2025/2165–2180 MHz bands, we note that coordination of satellite and terrestrial use with Canada and Mexico will be necessary. Finally, we are not reaching decisions here on several other issues raised in the *Further Notice,* 66 FR 47618, September 13, 2001, such as the consolidation of MSS assignments and BAS and FS relocation issues. We will address those issues in further proceedings. We note, for example, that relocating incumbent BAS operations in the 1990–2025 MHz band will be further complicated by our decision here. As we stated in the *Further Notice* when discussing possible reallocation of spectrum in the 1990–2025 MHz band, the relocation of BAS from any portion of the band would be shared between new MSS entrants and other new entrants in the band. Although we conclude that this principle would apply as a consequence of our reallocation decision, we will address fully BAS relocation issues in a future separate proceeding. We intend to address the relocation issues well in advance of the September 6, 2003, expiration of the initial two-year mandatory negotiation period for Phase 1 of the relocation plan between MSS and BAS.

8. This *Second Memorandum Opinion and Order* addresses a petition for rule making filed by CTIA on May 18, 2001, requesting that the 2 GHz MSS bands be reallocated for other uses (such as terrestrial wireless services) and also asking that the Commission withhold grant of 2 GHz MSS licenses. In the *Further Notice,* we granted the petition insofar as we proposed to reallocate 10–14 megahertz of spectrum for AWS, and denied it insofar as it requested reallocation of the entire 2 GHz MSS band and delaying of the licensing of MSS systems in the band. We stated that our actions in the *Further Notice* would better serve the public with respect to these issues and was consistent with the International Bureau's granting of the MSS licenses on July 17, 2001. In its petition for reconsideration, CTIA claims we made an error by acting on its petition without first placing it on public notice, and asks that we vacate our decision to reject its petition for rulemaking, place the petition on public notice, and consider it *ab initio.* CTIA also claims that we failed to articulate a reasoned decision for rejecting its request and, further, that we could not reasonably rely on the grant of the MSS licenses because that action prejudged our consideration of CTIA's petition.

9. Although we did not place CTIA's petition on public notice, our decision in that regard did not prejudice CTIA. We note that various parties filed responsive comments addressing reallocation of the entire 2 MSS GHz band in IB Docket No. 99–81, which demonstrates that the public was provided the opportunity to submit comment on the reallocation question raised by CTIA's petition, and did so. Moreover, the Commission has already raised and duly considered this reallocation question. The same day the Commission adopted the *Further Notice* that considered the reallocation of some MSS spectrum, it initiated a separate proceeding to explore whether MSS licensees should be afforded additional flexibility. Together, these proceedings explored the larger issue of MSS use that is also reflected in CTIA's petition. The *Third R&O* we adopted concludes that a portion of the MSS spectrum should be reallocated to support AWS, but rejects a complete reallocation of the band. Accordingly, CTIA's original petition for rule making is now moot,

and we deny its petition for reconsideration.

**Final Regulatory Flexibility Analysis**

10. As required by the Regulatory Flexibility Act (RFA) [1] an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rulemaking and Order* (NPRM),[2] as well as the *Memorandum Opinion and Order and Further Notice of Proposed Rule Making* (Further NPRM).[3] The Commission sought written public comments on the proposals in the NPRM and Further NPRM, including comment on each IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.[4]

**Need for, and Objectives of, the Third Report and Order**

11. The *Third Report and Order (Third R&O)* continues our efforts to allocate spectrum that can be used for the provision of advanced wireless services (AWS) to the public, which in turn supports our obligations under Section 706 of the 1996 Telecommunication Act [5] and, more generally, serves the public interest by promoting rapid and efficient radio communication facilities.

12. The *Third R&O* discusses the need for spectrum allocations of sufficient size and with particular characteristics so as to allow for the provision of AWS. Specifically, it evaluates spectrum that was formerly allocated to the Mobile-Satellite Service (MSS). The Commission previously concluded that 2 GHz MSS licensees could operate using a smaller amount of spectrum than that which had previously been allocated. The *Third R&O* allocates spectrum for fixed and mobile services (which could be made available for AWS) in the 1990–2000 MHz, 2020–2025 MHz, and 2165–2180 MHz bands.

**Summary of Significant Issues Raised by Public Comments in Response to the IRFA**

13. There were no comments filed that specifically addressed the rules and policies proposed in the IRFA.

**Description and Estimate of the Number of Small Entities to Which the Rules Will Apply**

14. The RFA directs agencies to provide a description of, and, where feasible, an estimate of, the number of small entities that may be affected by the rules adopted herein.[6] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' [7] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[8] A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).[9]

15. A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' [10] Nationwide, as of 1992, there were approximately 275,801 small organizations.[11] ''Small governmental jurisdiction'' generally means ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.'' [12] As of 1992, there were approximately 85,006 governmental entities in the United States.[13] This number includes 38,978 counties, cities, and towns; of these, 37,566, or 96%, have populations of fewer then 50,000.[14] The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, we estimate that 81,600 (96%) are small entities.

*Radiotelephone Operators.* The Commission has not developed service rules for AWS spectrum, nor has it attempted to categorize potential licensees for this spectrum. However, because many of the comments we received in support of our efforts to allocate spectrum for AWS were submitted by commercial radiotelephone operators and because licensees of AWS-like bands in other countries include incumbent commercial radiotelephone operators, we believe that there is a high likelihood that the class of AWS licensees may ultimately consist of one or more radiotelephone operator. Therefore, we examine this category in greater depth. The SBA has developed a small business size standard for small businesses in the category ''Cellular and Other Wireless Telecommunications.'' [15] Under that SBA category, a business is small if it has 1,500 or fewer employees.[16] According to the Bureau of the Census, only twelve firms from a total of 1238 cellular and other wireless telecommunications firms operating during 1997 had 1,000 or more employees.[17] Therefore, even if all twelve of these firms were cellular telephone companies, nearly all cellular carriers were small businesses under the SBA's definition. In addition, we note that there are 1807 cellular licenses; however, a cellular licensee may own several licenses. According to the most recent *Trends in Telephone Service* data, 858 carriers reported that they were engaged in the provision of either cellular service, Personal Communications Service (PCS), or Specialized Mobile Radio telephony services, which are placed together in that data. We have estimated that 291 of these are small under the SBA small business size standard.[18] Accordingly, based on this data, we estimate that not more than 291 radiotelephone operators

[1] *See* 5 U.S.C. 603. The RFA (codified at 5 U.S.C. 601–612) has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, Title II, 110 Stat. 857 (1996).

[2] Amendment of Part 2 of the Commission's Rules to Allocate Spectrum Below 3 GHz for Mobile and Fixed Services to Support the Introduction of New Advanced Wireless Services, Including Third Generation Wireless Systems, ET Docket No. 00–258, Notice of Proposed Rulemaking and Order, 16 FCC Rcd 596 (2001), 66 FR 18740, April 11, 2001.

[3] Amendment of Part 2 of the Commission's Rules to Allocate Spectrum Below 3 GHz for Mobile and Fixed Services to Support the Introduction of New Advanced Wireless Services, including Third Generation Wireless Systems, ET Docket No. 00–258, ET Docket No. 95–18, and IB Docket No. 99–81, Memorandum Opinion and Order, 66 FR 47518, September 13, 2001, and Further Notice of Proposed Rule Making, 16 FCC Rcd 16043 (2001), 66 FR 47618, September 13, 2001.

[4] *See* 5 U.S.C. 604.

[5] Section 706 of the Communications Act of 1934, as amended, codified at 47 U.S.C. 157.

[6] 5 U.S.C. 604(a)(3).

[7] 5 U.S.C. 601(6).

[8] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small-business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[9] 15 U.S.C. 632.

[10] 5 U.S.C. 601(4).

[11] Department of Commerce, U.S. Bureau of the Census, 1992 Economic Census, Table 6 (special tabulation of data under contract to Office of Advocacy of the U.S. Small Business Administration).

[12] 5 U.S.C. 601(5).

[13] U.S. Dept. of Commerce, Bureau of the Census, ''1992 Census of Governments.''

[14] *Id.*

[15] 13 CFR 121.201, North American Industry Classification System (NAICS) code 513322.

[16] *Id.*

[17] U.S. Department of Commerce, U.S. Census Bureau, 1997 Economic Census, Information—Subject Series, Establishment and Firm Size, Table 5—Employment Size of Firms Subject to Federal Income Tax at 64, NAICS code 513322 (October 2000).

[18] See Trends in Telephone Service, Industry Analysis and Technology Division, Wireline Communications Bureau, Table 5.3, page 5–5 (May 2002).

would be affected by a decision to make additional spectrum available for AWS.

*Geostationary, Non-Geostationary Orbit, Fixed Satellite, or Mobile Satellite Service Operators (including 2 GHz MSS systems).* The Commission has not developed a definition of small entities applicable to geostationary or non-geostationary orbit, fixed-satellite or mobile-satellite service operators. The SBA has developed a small business size standard for Satellite Telecommunications Carriers, which consists of all such companies having $12.5 million or less in annual receipts.[19] In addition, a second SBA size standard for Other Telecommunications includes ''facilities operationally connected with one or more terrestrial communications systems and capable of transmitting telecommunications to or receiving telecommunications from satellite systems,'' [20] and also has a size standard of annual receipts of $12.5 million or less. According to Census Bureau data for 1997, there were 324 firms in the category Satellite Telecommunications, total, that operated for the entire year.[21] Of this total, 273 firms had annual receipts of $5 million to $9,999,999 and an additional 24 firms had annual receipts of $10 million to $24,999,990.[22] Thus, under this size standard, the majority of firms can be considered small. In addition, according to Census Bureau data for 1997, there were 439 firms in the category Satellite Telecommunications, total, that operated for the entire year.[23] Of this total, 424 firms had annual receipts of $5 million to $9,999,999 and an additional 6 firms had annual receipts of $10 million to $24,999,990.[24] Thus, under this second size standard, the majority of firms can be considered small.

[19] 13 CFR 121.201, North American Industry Classification System (NAICS) code 517410 (formerly 513340).

[20] *Id.* NAICS code 517910 (formerly 513390).

[21] U.S. Census Bureau, 1997 Economic Census, Subject Series: Information, ''Receipt Size of Firms Subject to Federal Income Tax: 1997,'' Table 4, NAICS code 517410 (issued Oct. 2000).

[22] *Id.*

[23] U.S. Census Bureau, 1997 Economic Census, Subject Series: Information, ''Receipt Size of Firms Subject to Federal Income Tax: 1997,'' Table 4, NAICS code 517910 (issued Oct. 2000).

[24] *Id.*

**Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements**

16. The *Third R&O* addresses the possible use of frequency bands below 3 GHz to support the introduction of new AWS, but does not propose service rules. Thus, the item contains no new reporting, recordkeeping, or other compliance requirements.

**Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered**

17. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.'' [25]

18. Providing spectrum to support the introduction of new advanced mobile and fixed terrestrial wireless services is critical to the continuation of technological advancement. First and foremost, the Commission believes that providing for expanded use of the frequency bands identified in the *Third R&O* in order to allow for a wide range of voice, data, and broadband services over a variety of mobile and fixed networks will provide substantial new opportunities for small entities, including (but not limited to) small entities that are radiotelephone operators.

19. In prior decisions, we determined that MSS operations could exist within a 40 megahertz allocation, and this spectrum is not at issue in the current proceeding. Instead, the *Third R&O* addresses the use of 30 megahertz of abandoned MSS spectrum (*i.e.* spectrum available for reallocation because licensees either failed to satisfy Commission rules pertaining to system construction or because they voluntarily relinquished their authorizations). For this spectrum, we contrast the public benefits of the allocation of AWS and the potential that small entities will be involved in the provision of AWS with the likelihood that, at the time of MSS system implementation, no small businesses will be providing MSS. For this reason, we believe that the reallocation of spectrum from MSS in the *Third R&O* will actually provide small entities with opportunities that would have otherwise been unavailable.

[25] 5 U.S.C. 603(c)(1)–(c)(4).

**Report to Congress**

20. The Commission will send a copy of the Third Report and Order including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act.[26] In addition, the Commission will send a copy of the Third Report and Order, including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the Third Report and Order and FRFA (or summaries thereof) will also be published in the **Federal Register**.[27]

**List of Subjects**

*47 CFR Part 2*

Communications equipment.

*47 CFR Part 25*

Communications equipment, Satellites.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

**Rule Changes**

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 2 and 25 to read as follows:

## PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for part 2 continues to read as follows:

**Authority:** 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

2. Section 2.106 is amended as follows:

a. Revise pages 48 and 49 of the Table.

b. In the list of non-Federal Government (NG) footnotes, revise footnotes NG156 and NG168 and add footnotes NG177 and NG178.

The revisions and additions read as follows:

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[26] *See* 5 U.S.C. 801(a)(1)(A).

[27] *See* 5 U.S.C. 604(b).

## § 2.106 Table of Frequency Allocations.

| | | | | | |
|---|---|---|---|---|---|
| | | | 1755-1850<br>FIXED<br>MOBILE<br><br>G42 | 1755-1850 | |
| 5.149 5.341 5.385 5.386 5.387 5.388 | | | 1850-2025 | 1850-2000<br>FIXED<br>MOBILE<br><br>NG177 | RF Devices (15)<br>Personal Communications (24)<br>Fixed Microwave (101) |
| 1930-1970<br>FIXED<br>MOBILE 5.388A<br><br>5.388 | 1930-1970<br>FIXED<br>MOBILE 5.388A<br>Mobile-satellite (Earth-to-space)<br><br>5.388 | 1930-1970<br>FIXED<br>MOBILE 5.388A<br><br>5.388 | | | |
| 1970-1980<br>FIXED<br>MOBILE 5.388A<br><br>5.388 | | | | 2000-2020<br>MOBILE-SATELLITE (Earth-to-space)<br><br>NG156 | Satellite Communications (25) |
| 1980-2010<br>FIXED<br>MOBILE<br>MOBILE-SATELLITE (Earth-to-space) 5.351A<br><br>5.388 5.389A 5.389B 5.389F | | | | | |
| 2010-2025<br>FIXED<br>MOBILE 5.388A<br><br>5.388 | 2010-2025<br>FIXED<br>MOBILE<br>MOBILE-SATELLITE (Earth-to-space)<br><br>5.388 5.389C 5.389D 5.389E 5.390 | 2010-2025<br>FIXED<br>MOBILE 5.388A<br><br>5.388 | | 2020-2025<br>FIXED<br>MOBILE<br><br>NG177 | |
| 2025-2110<br>SPACE OPERATION (Earth-to-space) (space-to-space)<br>EARTH EXPLORATION-SATELLITE (Earth-to-space) (space-to-space)<br>FIXED<br>MOBILE 5.391<br>SPACE RESEARCH (Earth-to-space) (space-to-space)<br><br>5.392 | | | 2025-2110<br>SPACE OPERATION (Earth-to-space) (space-to-space)<br>EARTH EXPLORATION-SATELLITE (Earth-to-space) (space-to-space)<br>SPACE RESEARCH (Earth-to-space) (space-to-space)<br><br>5.391 5.392 US90 US222 US346 US347 | 2025-2110<br>FIXED NG23 NG118<br>MOBILE 5.391<br><br>5.392 US90 US222 US346 US347 | TV Auxiliary Broadcasting (74F)<br>Cable TV Relay (78)<br>Local TV Transmission (101J) |

| 2110-2345 MHz (UHF) | | | | | Page 49 |
|---|---|---|---|---|---|
| International Table | | | United States Table | | FCC Rule Part(s) |
| Region 1 | Region 2 | Region 3 | Federal Government | Non-Federal Government | |
| 2110-2120<br>FIXED<br>MOBILE 5.388A<br>SPACE RESEARCH (deep space) (Earth-to-space)<br><br>5.388 | | | 2110-2120<br><br>US252 | 2110-2155<br>FIXED NG23<br>MOBILE<br><br>US252 | Domestic Public Fixed (21)<br>Public Mobile (22)<br>Fixed Microwave (101) |
| 2120-2160<br>FIXED<br>MOBILE 5.388A<br><br>5.388 | 2120-2160<br>FIXED<br>MOBILE 5.388A<br>Mobile-satellite (space-to-Earth)<br><br>5.388 | 2120-2170<br>FIXED<br>MOBILE 5.388A | 2120-2200 | 2155-2160<br>FIXED NG23 | Domestic Public Fixed (21)<br>Fixed Microwave (101) |
| 2160-2170<br>FIXED<br>MOBILE 5.388A<br><br>5.388 5.392A | 2160-2170<br>FIXED<br>MOBILE<br>MOBILE-SATELLITE (space-to-Earth)<br><br>5.388 5.389C 5.389D 5.389E 5.390 | 5.388 | | 2160-2180<br>FIXED NG23 NG153<br>MOBILE<br><br>NG178 | Domestic Public Fixed (21)<br>Public Mobile (22)<br>Fixed Microwave (101) |
| 2170-2200<br>FIXED<br>MOBILE<br>MOBILE-SATELLITE (space-to-Earth) 5.351A<br><br>5.388 5.389A 5.389F 5.392A | | | | 2180-2200<br>MOBILE-SATELLITE (space-to-Earth)<br><br>NG23 NG168 | Satellite Communications (25) |
| 2200-2290<br>SPACE OPERATION (space-to-Earth) (space-to-space)<br>EARTH EXPLORATION-SATELLITE (space-to-Earth) (space-to-space)<br>FIXED<br>MOBILE 5.391<br>SPACE RESEARCH (space-to-Earth) (space-to-space) | | | 2200-2290<br>SPACE OPERATION (space-to-Earth) (space-to-space)<br>EARTH EXPLORATION-SATELLITE (space-to-Earth) (space-to-space)<br>FIXED (line-of-sight only) | 2200-2290 | |

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* * * * *

**Non-Federal Government (NG) Footnotes**

* * * * *

NG156 The band 2000–2020 MHz is also allocated to the fixed and mobile services on a primary basis for facilities where the receipt date of the initial application was prior to June 27, 2000, and on a secondary basis for all other initial applications. Not later than September 6, 2010, the band 2000–2020 MHz is allocated to the fixed and mobile services on a secondary basis.

* * * * *

NG168 The band 2180–2200 MHz is also allocated to the fixed and mobile services on a primary basis for facilities where the receipt date of the initial application was prior to January 16, 1992, and on a secondary basis for all other initial applications. Not later than September 6, 2010, the band 2180–2200 MHz is allocated to the fixed and mobile services on a secondary basis.

* * * * *

NG177 In the bands 1990–2000 MHz and 2020–2025 MHz, where the initial filing date for facilities in the fixed and mobile services was prior to June 27, 2000, said facilities shall operate on a primary basis and all later-applied-for facilities shall operate on a secondary basis to Advanced Wireless Services. Not later than September 6, 2010, all such facilities in the bands 1990–2000 MHz and 2020–2025 MHz shall operate on a secondary basis to Advanced Wireless Services.

NG178 In the band 2165–2180 MHz, where the initial filing date for facilities in the fixed and mobile services was prior to January 16, 1992, said facilities shall operate on a primary basis and all later-applied-for facilities shall operate on a secondary basis to Advanced Wireless Services. Not later than September 6, 2010, all such facilities in the band 2165–2180 MHz shall operate on a secondary basis to Advanced Wireless Services.

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## PART 25—SATELLITE COMMUNICATIONS

3. The authority citation for part 25 continues to read as follows:

**Authority:** 47 U.S.C. 701–774. Interprets or applies sections 4, 301, 302, 303, 307, 309 and 332 of the Communications Act, as amended, 47 U.S.C. Sections 154, 301, 302, 303, 307, 309 and 332, unless otherwise noted.

4. Section 25.201 is amended by revising the definition for ''2 GHz Mobile-Satellite Service'' to read as follows:

**§ 25.201 Definitions.**

* * * * *

*2 GHz Mobile Satellite Service.* A mobile-satellite service that operated in the 2000–2020 MHz and 2180–2200 MHz frequency bands, or in any portion thereof.

* * * * *

5. Section 25.202 is amended by revising paragraph (a)(4)(ii) to read as follows:

**§ 25.202 Frequencies, frequency tolerance and emission limitations.**

(a) * * *

(4) * * *

(ii) The following frequencies are available for use by the 2 GHz Mobile-Satellite Service: 2000–2020 MHz: User-to-Satellite Link; 2180–2200 MHz: Satellite-to-User Link.

* * * * *

[FR Doc. 03–6039 Filed 3–12–03; 8:45 am]

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[DA 03–587; MB Docket No. 02–127; RM–10449]**

## Radio Broadcasting Services; Roundup, MT

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Audio Division, at the request of William J. Edwards, allots Channel 248A at Roundup, Montana, as the community's first local FM service. Channel 248A can be allotted to Roundup, Montana, in compliance with the Commission's minimum distance separation requirements with a site restriction of 1.08 km (0.6 miles) northeast of Roundup. The coordinates for Channel 248A at Roundup, Montana, are 46–26–58 North Latitude and 108–31–44 West Longitude. The Canadian government has concurred in this allotment. A filing window for Channel 248A at Roundup, MT, will not be opened at this time. Instead, the issue of opening this allotment for auction will be addressed by the Commission in a subsequent Order.

**DATES:** Effective April 18, 2003.

**FOR FURTHER INFORMATION CONTACT:** Deborah Dupont, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 02–127, adopted February 26, 2003, and released March 4, 2003. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

**List of Subjects in 47 CFR part 73**

Radio, Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Montana, is amended by adding Roundup, Channel 248A.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 03–6095 Filed 3–12–03; 8:45 am]

BILLING CODE 6712–01–P

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[DA 03–586; MM Docket No. 01–227, RM–10255]**

## Radio Broadcasting Services; Reydon, OK

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Audio Division, at the request of Katherine Pyeatt, allots Channel 264C2 to Reydon, Oklahoma, as the community's first local aural broadcast service. *See* 66 FR 48108, September 18, 2001. Channel 264C2 can be allotted to Reydon in compliance with the Commission's minimum distance separation requirements, provided there is a site restriction of 29.9 kilometers (18.6 miles) south of Reydon. The reference coordinates for Channel 264C2 at Reydon are 35–23–11

North Latitude and 99–52–38 West Longitude. A filing window for Channel 264C2 at Reydon, Oklahoma, will not be opened at this time. Instead, the issue of opening a filing window for this channel will be addressed by the Commission in a subsequent order.

**DATES:** Effective April 18, 2003.

**ADDRESSES:** Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Rolanda F. Smith, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MM Docket Nos. 01–227, adopted February 26, 2003, and released March 4, 2003. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Oklahoma, is amended by adding Reydon, Channel 264C2.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 03–6094 Filed 3–12–03; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 679

**[Docket No. 021122286–3036–02; I.D. 030703A]**

### Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 610 of the Gulf of Alaska

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

**ACTION:** Closure.

**SUMMARY:** NMFS is prohibiting directed fishing for pollock in Statistical Area 610 of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the B season allowance of the pollock total allowable catch (TAC) for Statistical Area 610 of the GOA.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), March 11, 2003, through 1200 hrs, A.l.t., August 25, 2003.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season allowance of the pollock TAC in Statistical Area 610 of the GOA is 2,894 metric tons (mt) as established by the final 2003 harvest specifications for groundfish of the GOA (68 FR 9924, March 3, 2003). In accordance with § 679.20(a)(5)(iii)(B) the Administrator, Alaska Region, NMFS (Regional Administrator) hereby reduces the B season pollock TAC by 1,228 mt, the amount of the harvest previously taken in excess of the A season pollock allowance in Statistical Area 610. The B season allowance of pollock TAC in Statistical Area 610 is 1,666 mt (2,894 mt minus 1,228 mt).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the B season allowance of the pollock TAC in Statistical Area 610 has been reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,466 mt, and is setting aside the remaining 200 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 610 of the GOA.

Maximum retainable amounts may be found in the regulations at § 679.20(e) and (f).

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the TAC, and therefore reduce the public's ability to use and enjoy the fishery resource.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by section 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: March 7, 2003.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 03–6103 Filed 3–10–03; 2:27 pm]

BILLING CODE 3510–22–S

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 679

**[Docket No. 021122286–3036–02; I.D. 030703B]**

### Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 630 of the Gulf of Alaska

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

**ACTION:** Closure.

**SUMMARY:** NMFS is prohibiting directed fishing for pollock in Statistical Area

630 of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the B season allowance of the pollock total allowable catch (TAC) for Statistical Area 630 of the GOA.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), March 10, 2003, through 1200 hrs, A.l.t., August 25, 2003.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season allowance of the pollock TAC in Statistical Area 630 is 1,031 metric tons (mt) as established by the final 2003 harvest specifications for groundfish of the GOA (68 FR 9924, March 3, 2003). In accordance with § 679.20(a)(5)(iii)(B) the Administrator, Alaska Region, NMFS (Regional Administrator) hereby reduces the B season pollock TAC by 174 mt, the amount of the harvest previously taken in excess of the A season pollock allowance in Statistical Area 630. The B season allowance of pollock TAC in Statistical Area 630 is 857 mt (1,031 mt minus 174 mt).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the B season allowance of the pollock TAC in Statistical Area 630 is necessary as incidental catch to support other anticipated groundfish fisheries. Consequently, the Regional Administrator establishes the B season directed fishing allowance as zero. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 630 of the GOA.

Maximum retainable amounts may be found in the regulations at § 679.20(e) and (f).

## Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the TAC, and therefore reduce the public's ability to use and enjoy the fishery resource.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by section 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: March 7, 2003.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 03–6104 Filed 3–10–03; 2:27 pm]

BILLING CODE 3510–22–S

# Proposed Rules

Federal Register
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Thursday, March 13, 2003

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 AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 1230

**[No. LS–02–15]**

## Pork Promotion, Research, and Consumer Information Program: Submission of Information

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** Pursuant to the Pork Promotion, Research, and Consumer Information Act of 1985 (Act) and the Pork Promotion, Research, and Consumer Information Order (Order) issued thereunder, this proposed rule would add a section to the regulations that implement the Order to require remitters of pork checkoff assessments, upon request by the Department of Agriculture (USDA), to submit to the Agricultural Marketing Service (AMS) the names, addresses, and any other information deemed necessary to identify persons from whom assessments were collected. This action is necessary in order to obtain the information necessary to conduct a survey of eligible producers and importers no earlier than June 2003 to determine if they favor a referendum on the Pork Checkoff Program. AMS agreed to conduct a survey as part of a settlement of litigation against USDA filed by the Michigan Pork Producers Association (MPPA) and the National Pork Producers Council. The information that would be collected through this action would be used to establish the total number of pork producers and importers that would be utilized in determining whether the 15 percent threshold requirement contained in the Act for conducting a referendum has been met.

**DATES:** Written comments on this proposed rule must be received by May 12, 2003.

**ADDRESSES:** Send copies of comments to Kenneth R. Payne, Chief; Marketing Programs Branch, Room 2638–S; Livestock and Seed Program; Agricultural Marketing Service, USDA; STOP–0251; 1400 Independence Avenue, SW.; Washington, DC 20250–0251. Comments may also be sent by e-mail to *porkcomments@usda.gov* or by fax to 202/720–1125. State that your comments refer to Docket No. LS–02–15. Comments received may be inspected at this location between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays, or on the Internet at *www.ams.usda.gov/lsg/mpb/rp-pork.htm.*

Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35)(PRA), also send comments regarding the merits of the burden estimate, ways to minimize the burden, including through the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information to the above address. Comments concerning the information collection requirements contained in this proposed rule should also be sent to the Offices of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17th Street, NW., Room 725, Washington, DC 20503, Attention: Desk Officer for Agriculture.

**FOR FURTHER INFORMATION CONTACT:** Kenneth R. Payne, Chief, Marketing Programs Branch on 202/720–1115, fax 202/720–1125, or by e-mail at *kenneth.payne@usda.gov.*

**SUPPLEMENTARY INFORMATION:**

### Executive Order 12866 and 12988 and Regulatory Flexibility Act and the Paperwork Reduction Act

The Office of Management and Budget has waived the review process required by Executive Order 12866 for this action.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have a retroactive effect. The Act states that the statute is intended to occupy the field of promotion and consumer education involving pork and pork products and of obtaining funds thereof from pork producers and that the regulation of such activity (other than a regulation or requirement relating to a matter of public health or the provision of State or local funds for such activity) that is in addition to or different from the Act may not be imposed by a State. The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under § 1625 of the Act, a person subject to an Order may file a petition with the Secretary stating that such Order, a provision of such Order or an obligation imposed in connection with such Order is not in accordance with law; and requesting a modification of the Order or an exemption from the Order. Such person is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in the district in which the person resides or does business has jurisdiction to review USDA's determination, if a complaint is filed not later than 20 days after the date such person receives notice of such determination.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA)(5 U.S.C. 601 *et seq.*), AMS has considered the economic effect of this proposed action on small entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened. The National Pork Board (Board), which receives the pork checkoff assessments, estimated that in calendar year 2001, there were approximately 3,173 entities that remitted pork checkoff assessments. Many of these entities which include packers, auction markets, county fairs, and individual pork producers should be classified as small entities under the criteria established by the Small Business Administration (SBA)(13 CFR 121.201). SBA defines small agricultural producers as those having annual receipts of less than $750,000, small agricultural service firms as those whose annual receipts are less than $5 million, and small meat packers as those that have less than 500 employees.

This proposed rule would require, upon request by USDA, remitters of pork checkoff assessments to submit to AMS the names, addresses, and any other information deemed necessary to identify persons from whom assessments were collected. This information would be available from existing records. The information collection requirements, as discussed

below, would be minimal. It is anticipated that much of the required information would be able to be submitted electronically and would not be a significant burden. Accordingly, AMS has determined that this proposed rule will not have a significant economic impact on a substantial number of small business entities.

**Paperwork Reduction Act**

In accordance with the OMB regulation (5 CFR part 1320) that implements the PRA (44 U.S.C. chapter 35), the information collection requirements are being submitted to OMB for approval.

*Title:* Pork Promotion, Research, and Consumer Information Program: Submission of Information.

*OMB Number:* 0581-new collection.

*Expiration Date of Approval:* 3 years from date of approval.

*Type of Request:* Approval of new information collection.

*Abstract:* The purpose of this proposed rule is to add a section to the regulations that implement the Order that would require remitters of pork checkoff assessments, upon request by USDA, to submit to AMS the names, addresses, and any other information deemed necessary to identify persons from whom assessments were collected. There is no form to fill out. The necessary information to be submitted either electronically, e-mail, facsimile, or by mail may done so in any format or style.

Based on estimates provided by the Board, there are approximately 3,173 entities that remitted pork checkoff assessments in calendar year 2001.

It is anticipated that many of these entities maintain their records electronically and have a person on staff to operate and manage their computer system. The only costs that would be incurred by these entities in complying with this request would be the labor hours required to retrieve the pertinent information from the computer system and transmit it electronically to AMS. AMS estimates the time required to complete this task to be 1 hour per respondent at a cost of $20 per hour.

For those entities that rely on an outside contractor to manage their computer system, there may be a one-time fee incurred for having the contractor retrieve the necessary information from the system and transmit it electronically to AMS. AMS estimates the time required to complete this task to be 2 hours per respondent at a cost of $50 per hour.

For those entities that do not maintain their records electronically, it is anticipated that such entities would review their paper records, compile the necessary information, and submit it to AMS via facsimile or mail. AMS estimates the time required to complete this task to be 4 hours per respondent at a cost of $20 per hour. AMS estimates the total cost in complying with this request would be $241,320.

In this proposed rule, information collection requirements include the following:

(1) Electronic submission of information by entities that have personnel on staff to operate and manage their computer system.

*Estimate of Burden:* The public reporting burden for this collection of information is estimated to average 1 hour per response.

*Respondents:* Packers, auction markets, county fairs, and individual producer entities.

*Estimated Number of Respondents:* 271.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 271 hours.

*Total Cost:* $5,420.

(2) Electronic submission of information by entities that rely on an outside contractor to manage their computer system.

*Estimate of Burden:* The public reporting burden for this collection of information is estimated to average 2 hours per response.

*Respondents:* Packers, auction markets, county fairs, and individual producer entities.

*Estimated Number of Respondents:* 187.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 374 hours.

*Total Cost:* $18,700.

(3) Submission of information by those entities that do not maintain their records electronically.

*Estimate of Burden:* The public reporting burden for this collection of information is estimated to average 4 hours per response.

*Respondents:* Packers, auction markets, county fairs, and individual producer entities.

*Estimated Number of Respondents:* 2,715.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Total Annual Burden on Respondents:* 10,860 hours.

*Total Cost:* $217,200.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility; (2) 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) 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 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.

OMB is required to make a decision concerning the collection of information contained in this rule between 30 days and 60 days after publication. Therefore, a comment to OMB is best assured of being considered if OMB receives it within 30 days after publication.

**Background**

The Act (7 U.S.C. 4801–4819) approved December 23, 1985, authorized the establishment of a national pork promotion, research, and consumer information program. The final Order establishing a pork promotion, research, and consumer information program was published in the September 5, 1986, issue of the **Federal Register** (51 FR 31898; as corrected, at 51 FR 36383 and amended at 53 FR 1909, 53 FR 30243, 56 FR 4, 56 FR 51635, 60 FR 29963, 61 FR 29002, 62 FR 26205, 63 FR 45936, 64 FR 44643, 66 FR 67071, 67 FR 47474, and 67 FR 58320) and assessments began on November 1, 1986. The program was funded by an initial assessment rate of 0.25 percent of the market value of all porcine animals marketed in the United States and on imported porcine animals with an equivalent assessment on pork and pork products. However, that rate was increased to 0.35 percent effective December 1, 1991 (56 FR 51635), to 0.45 percent effective September 3, 1995 (60 FR 29963), and was decreased to 0.40 percent effective September 30, 2002 (67 FR 58320).

Section 1230.80 of the Order requires each person that is responsible for collecting or remitting any assessment under § 1230.71(b) to report the quantity and market value of the animal subject to assessment, the amount of assessment collected, the month the assessment was collected, the State where the animal was produced, and ''Such other information as may be required by regulations * * *'' Accordingly, to assist AMS in its administration and oversight of the Pork Checkoff Program, particularly in conducting activities such as surveys and referendums, a new section would be added to the

regulations that would require remitters of pork checkoff assessments, upon request by USDA, to submit to AMS the names, addresses, and any other information deemed necessary to identify persons from whom assessments were collected.

As part of a settlement between USDA and MPPA, *et al.*, USDA agreed to conduct a survey of eligible producers and importers (no earlier than June 2003) to determine whether 15 percent of eligible producers and importers favor a referendum on the Pork Checkoff Program. The information that would be collected through this action may be used to establish the total number of pork producers that would be utilized in determining whether the 15 percent threshold requirement contained in the Act for conducting a referendum has been met. Further, the information could be used in subsequent referenda to determine the number of eligible producers.

### List of Subjects in 7 CFR Part 1230

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreement, Meat and meat products, Pork and pork products.

For the reasons set forth in the preamble, it is proposed that 7 CFR part 1230 be amended as follows:

## PART 1230—PORK PROMOTION, RESEARCH, AND CONSUMER INFORMATION

1. The authority citation for 7 CFR part 1230 continues to read as follows:

**Authority:** 7 U.S.C. 4801–4819.

2. Section 1230.121 would be added to read as follows:

### § 1230.121 Submission of Information.

Pursuant to the provisions of § 1230.80, at the request of the Secretary, each person responsible for collecting and remitting assessments to the Board, shall submit the names, addresses, and any other information deemed necessary to identify persons from whom assessments were collected to the Department.

Dated: March 11, 2003.

**A.J. Yates,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 03–6163 Filed 3–11–03; 12:59 pm]

BILLING CODE 3410–02–P

## DEPARTMENT OF AGRICULTURE

## Animal and Plant Health Inspection Service

## 9 CFR Part 94

**[Docket No. 00–080–2]**

## Availability of Evaluation Related to Hog Cholera (Classical Swine Fever) Status of East Anglia

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** We are advising the public that an evaluation has been prepared by the Animal and Plant Health Inspection Service concerning the hog cholera (classical swine fever) status of East Anglia, a region of England that includes the counties of Essex, Norfolk, and Suffolk, and the related disease risks associated with importing animals and animal products into the United States from East Anglia. This evaluation will be used as a basis for determining whether to relieve certain prohibitions and restrictions on the importation of pork and pork products and swine into the United States from East Anglia. We are making this evaluation available to the public for review and comment.

**DATES:** We will consider all comments that we receive on or before May 12, 2003.

**ADDRESSES:** You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 00–080–2, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 00–080–2. If you use e-mail, address your comment to *regulations@aphis.usda.gov.* Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 00–080–2'' on the subject line.

You may read any comments that we receive on the evaluation 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.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

**FOR FURTHER INFORMATION CONTACT:** Dr. Charisse Cleare, Senior Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4928.

**SUPPLEMENTARY INFORMATION:**

### Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States in order to prevent the introduction of various animal diseases, including rinderpest, foot-and-mouth disease, African swine fever, hog cholera (classical swine fever), and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine. Section 94.9 of the regulations restricts the importation into the United States of pork and pork products from regions where hog cholera is known to exist. Section 94.10 of the regulations, with certain exceptions, prohibits the importation of swine that originate in or are shipped from or transit any region in which hog cholera is known to exist. The regulations in §§ 94.9(a) and 94.10(a) provide that hog cholera exists in all regions of the world except for certain regions listed in those sections.

In an interim rule effective August 4, 2000, and published in the **Federal Register** on September 20, 2000 (65 FR 56774–56775, Docket No. 00–080–1), we amended the regulations by removing East Anglia (a region of England that includes Essex, Norfolk, and Suffolk counties) from the lists of regions considered to be free of hog cholera. That action was necessary because hog cholera had been confirmed in this region. The effect of the interim rule was to restrict the importation of pork and pork products and to prohibit the importation of swine into the United States from East Anglia.

Although we removed East Anglia from the list of regions considered to be free of hog cholera, we recognized that Great Britain's Ministry of Agriculture, Fisheries and Food, now part of the Department for Environment, Food, and Rural Affairs, immediately responded to the detection of hog cholera by initiating measures to eradicate the disease. We stated that we intended to reassess the situation in the region at a future date

in accordance with Office International des Epizooties standards, and that as part of that reassessment process, we would consider all comments received regarding the interim rule.

Additionally, we stated that the future assessment would enable us to determine whether it was necessary to continue to prohibit the importation of swine and to restrict the importation of pork and pork products from East Anglia, or whether we could restore East Anglia to the list of regions in which hog cholera is not known to exist.

In this notice, we are announcing the availability for review and comment of a document entitled ''APHIS Evaluation of the Classical Swine Fever Status of East Anglia (counties of Norfolk, Suffolk, and Essex) November 2002.'' This evaluation assesses the hog cholera (classical swine fever) status of East Anglia and the related disease risks associated with importing animals and animal products into the United States from East Anglia. This evaluation will serve as a basis for our determination whether to relieve certain prohibitions and restrictions on the importation of swine and pork and pork products into the United States from East Anglia. We are making the evaluation available for public comment for 60 days.

You may view the evaluation in our reading room (information on the location and hours of the reading room is provided under the heading **ADDRESSES** at the beginning of this notice). You may also request a copy by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT.** Please refer to the title of the evaluation when requesting copies.

You may also view the evaluation on the Internet at *http://www.aphis.usda.gov/vs/ncie/reg-request.html.* At the bottom of the website page, click on ''Information previously submitted by Regions requesting export approval and their supporting documentation.'' At the next screen, click on the triangle beside ''European Union/Not Specified/Classical Swine Fever,'' then on the triangle beside ''Response by APHIS.'' A link will then appear for ''APHIS Evaluation of Classical Swine Fever Status of East Anglia (counties of Norfolk, Suffolk, and Essex) November 2002.'' Following that link will allow you to view the evaluation.

**Authority:** 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 7th day of March, 2003.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 03–6059 Filed 3–12–03; 8:45 am]

**BILLING CODE 3410–34–P**

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 39

**[Docket No. 2002–NE–22–AD]**

**RIN 2120–AA64**

## Airworthiness Directives; Titeflex Corporation

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** The Federal Aviation Administration (FAA) proposes to adopt a new airworthiness directive (AD) that is applicable to certain Titeflex Corporation hoses installed on Boeing 737–300, –400, –500, –600, –700, –700C, –800, –900, 747–400, 757–200, –300, 767–200, –300, and –300F airplanes. This proposal would require within 24 months after the effective date of the AD, inspection of certain Titeflex Corporation hoses for proper date and paint code, replacement if necessary, and if necessary, inspection for proper heat treatment of aluminum B-nuts. This proposal is prompted by certain Titeflex Corporation hoses discovered with incorrect heat treatment of B-nuts. The actions specified by the proposed AD are intended to prevent fire extinguishing system and fuel system hose failure due to improperly heat treated aluminum B-nuts.

**DATES:** Comments must be received by May 12, 2003.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002–NE–22–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may be inspected at this location, by appointment, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Comments may also be sent via the Internet using the following address: ''*9-ane-adcomment@faa.gov*''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3703, Seattle, Washington 98124–2207. This information may be examined, by appointment, at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

**FOR FURTHER INFORMATION CONTACT:** Terry Fahr, Aerospace Engineer, Boston Aircraft Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7155; fax (781) 238–7199.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2002–NE–22–AD.'' The postcard will be date stamped and returned to the commenter.

### Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002–NE–22–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

### Discussion

In March of 2001, the FAA became aware that some of the B-nuts on certain engine and cargo compartment fire extinguishing system hoses, and on certain fuel hoses, all manufactured by

Titeflex Corporation, delivered to Boeing from November 1999 through January 2001, are suspect for improper heat treatment. Improperly heat treated B-nuts can lead to stress corrosion B-nut failure, and inadequate fire protection and fuel leakage. This condition, if not corrected, could result in fire extinguishing system and fuel system hose failure due to improperly heat treated aluminum B-nuts.

**Manufacturer's Service Information**

The FAA has reviewed and approved the technical contents of the following Boeing alert service bulletins (ASBs):

- ASB 737–26A1108, Revision 1, dated June 27, 2002, applicable to 737–300, –400, and –500 airplanes, that describes procedures for inspecting and replacing if necessary, Titeflex Corporation hoses connected to engine and cargo compartment fire extinguishing bottles.
- ASB 737–26A1109, Revision 1, dated November 7, 2002, applicable to 737–600, –700, –700C, –800, and –900 airplanes, that describes procedures for inspecting and replacing if necessary, Titeflex Corporation hoses connected to engine, auxiliary power unit (APU), and cargo compartment fire extinguishing bottles, and wing-to-strut fuel hoses.
- ASB 747–26A2269, Revision 1, dated June 6, 2002, applicable to 747–400, that describes procedures for inspecting and replacing if necessary, Titeflex Corporation hoses connected to forward cargo and main deck cargo compartment fire extinguishing bottles.
- ASB 757–26A0043, Revision 1, dated November 14, 2002, applicable to 757–200 airplanes, that describes procedures for inspecting and replacing if necessary, Titeflex Corporation hoses connected to engine, APU, and cargo compartment fire extinguishing bottles.
- ASB 757–26A0044, Revision 1, dated November 14, 2002, applicable to 757–300 airplanes, that describes procedures for inspecting and replacing if necessary, Titeflex Corporation hoses connected to engine and cargo compartment fire extinguishing bottles.
- ASB 767–26A0121, dated December 19, 2001, applicable to 767–200, –300, and –300F airplanes, that describes procedures for inspecting and replacing if necessary, Titeflex Corporation hoses connected to cargo compartment fire extinguishing bottles.

**Differences Between This AD and the Manufacturer's Service Information**

Although the ASBs recommend performing the inspections and replacing unserviceable hoses within 12 months after the initial release dates of ASB 737–26A1108, ASB 737–26A1109, ASB 767–26A0121, and ASB 747–26A2269, and within 18 months after the initial release dates of ASB 757–26A0043 and ASB 757–26A0044, this proposal would require inspections and replacing unserviceable hoses to be done within 24 months after the effective date of the AD. This compliance time was substantiated by analysis by Boeing and coordinated between the FAA and Boeing to help coincide with parts availability.

**FAA's Determination of an Unsafe Condition and Proposed Actions**

Since an unsafe condition has been identified that is likely to exist or develop on other Titeflex Corporation hoses of the same type design, installed on Boeing 737–300, –400, –500, –600, –700, –700C, –800, –900, 747–400, 757–200, –300, 767–200, –300, and –300F airplanes, the proposed AD would require within 24 months after the effective date of the AD, inspection of hoses for proper date and paint code, replacement if necessary, and if necessary, inspection for proper heat treatment of aluminum B–nuts. The actions would be required to be done in accordance with the alert service bulletins described previously. This proposal has been coordinated with the FAA Transport Airplane Directorate.

**Economic Analysis**

The FAA estimates that 1,139 airplanes of U.S. registry would be affected by this proposed AD. The FAA also estimates that it would take approximately 35 work hours per airplane to perform the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $4,305 per engine. Based on these figures, the total cost of the proposed AD to U.S. operators is estimated to be $7,295,295.

**Regulatory Analysis**

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it 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. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that 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) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**The Proposed Amendment**

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding the following new airworthiness directive:

**Titeflex Corporation:** Docket No. 2002–NE–22–AD.

*Applicability:* This airworthiness directive (AD) is applicable to certain Titeflex Corporation hoses that are identified by Boeing part number (P/N), or for certain hoses, by Titeflex parts manufacturer approval (PMA) P/N in this AD. These hoses are used on, but not limited to Boeing 737–300, –400, –500, –600, –700, –700C, –800, and –900; 757–200 and –300; 767–200, –300, and –300F; and 747–400 airplanes.

**Note 1:** This AD applies to each hose identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For hoses that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance**

Compliance with this AD is required as indicated, unless already done.

To prevent fire extinguishing system and fuel system hose failure due to improperly heat treated aluminum B–nuts, do the following:

(a) Within 24 months after the effective date of this AD, inspect the manufacture date code on all hoses listed in Table 1 of this AD, in accordance with the Accomplishment Instructions of the applicable Boeing alert service bulletins (ASB) contained in Table 1 of this AD. Table 1 follows:

TABLE 1.—APPLICABLE HOSE P/NS

| Airplane model | Boeing hose p/n | Titeflex PMA p/n | Used for— | Applicable alert service bulletin— |
|---|---|---|---|---|
| (1) 737–300, –400, and –500 airplanes. | S312N512–5, S312N512–6, BACH5R0110YP, BACH5S0110XN. | 113701–5, 113701–6 .... | Engine and cargo compartment fire extinguishing bottles. | 737–26A1108, Revision 1, dated June 27, 2002. |
| (2) 737–600, –700, –700C, –800, and –900 airplanes. | S316A001–1, S316A001–2, S312N512–15, S312N512–17, S312N512–18, BACH5R0110YP, BACH5S0110XN. | 115398–1, 115398–2, 113701–15, 113701–17, 113701–18. | Engine, auxiliary power unit (APU), and cargo compartment fire extinguishing bottles, and wing-to-strut fuel hoses. | 737–26A1109, Revision 1, dated November 7, 2002. |
| (3) 747–400 airplanes .... | BACH5R0080YY, BACH5R0140YU, BACH5S0140XT, BACH5R0186YY, BACH5R0186XX, BACH5S0080XX, BACH5S0080YY, BACH5S0110XN. | ..... | Forward cargo and main deck cargo compartment fire extinguishing bottles. | 747–26A2269, Revision 1, dated June 6, 2002. |
| (4) 757–200 airplanes .... | S312N512–1, S312N512–2, S312N512–3, S312N512–4, BACH5R0110YP, BACH5S0110XN. | 113701–1, 113701–2, 113701–3, 113701–4. | Engine, APU, and cargo compartment fire extinguishing bottles. | 757–26A0043, Revision 1, dated November 14, 2002. |
| (5) 757–300 airplanes .... | S312N512–1, S312N512–2, S312N512–3, S312N512–4, BACH5R0110YP, BACH5S0074XN. | 113701–1, 113701–2, 113701–3, 113701–4. | Engine and cargo compartment fire extinguishing bottles. | 757–26A0044, Revision 1, dated November 14, 2002. |
| (6) 767–200, –300, and –300F airplanes. | BACH5R0085YU, BACH5R0140YU, BACH5S0077XT, BACH5S0140XT, BACH5S0184XX, BACH5R0127YY. | ..... | Cargo compartment fire extinguishing bottles. | 767–26A0121, dated December 19, 2001. |

(b) If the hose manufacture date code is before 11/99 or after 1/01, or if the manufacture date is 11/99 through 1/01 and there is a permanent white dot on the ID band, no further action is required for that hose.

(c) If the hose manufacture date code is 11/99 through 1/01 inclusive and there is no permanent white dot on the ID band, replace the hose with a serviceable hose or perform an indirect conductive inspection/test for proper heat treat, in accordance with the accomplishment instructions of the applicable ASB listed in Table 1 of this AD.

(d) Replace the hose with a serviceable hose if any B-nut is improperly heat treated.

**Credit for Previous Inspections**

(e) Previous inspections performed using ASB 737–26A1108, dated November 15, 2001, ASB 737–26A1109, dated November 15, 2001, ASB 747–26A2269, dated November 1, 2001, ASB 757–26A0043, dated November 15, 2001, and ASB 757–26A0044, dated November 15, 2001, comply with the inspection requirements of this AD.

**Alternative Methods of Compliance**

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Boston Aircraft Certification Office (ACO). Operators must submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Boston ACO.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Boston ACO.

**Special Flight Permits**

(g) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done.

Issued in Burlington, Massachusetts, on March 6, 2003.

**Jay J. Pardee,**

*Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 03–6043 Filed 3–12–03; 8:45 am]

BILLING CODE 4910–13–P

## COMMODITY FUTURES TRADING COMMISSION

## 17 CFR Part 4

## Performance Data and Disclosure for Commodity Trading Advisors

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Proposed rules.

**SUMMARY:** The Commodity Futures Trading Commission (''CFTC'' or ''Commission'') is proposing to amend its rules relating to the computation and presentation of rate of return information and other disclosures concerning partially-funded accounts managed by commodity trading advisors (''CTAs'').

**DATES:** Comments must be received by April 14, 2003.

**ADDRESSES:** Interested persons should submit their views and comments to Jean A. Webb, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. In addition, comments may be sent by facsimile transmission to (202) 418–5543, or by

electronic mail to *secretary@cftc.gov*. Reference should be made to ''Performance Data and Disclosure for Commodity Trading Advisors.''

**FOR FURTHER INFORMATION CONTACT:**

Robert B. Wasserman, Associate Director, (202) 418–5092, electronic mail: *rwasserman@cftc.gov*, or Eileen R. Chotiner, Futures Trading Specialist, (202) 418–5467, electronic mail: *echotiner@cftc.gov*, Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Commission is proposing to amend several of its rules [1] affecting the computation and presentation of rate of return information and other disclosures by CTAs to prospective clients. The proposed amendments will enable CTAs to disclose past performance as computed on the basis of the client's nominal account size (the amount upon which the CTA bases its trading decisions) rather than on the basis of the actual funds the client has placed in an account subject to the CTA's control. The amendments will affect past performance disclosure made by CTAs to prospective clients, and will not affect the manner in which information is provided to existing clients. Existing clients will continue to receive information on the status of their own accounts on an actual cash basis.[2]

On August 2, 1999, the Commission published in the **Federal Register** [3] proposed rules regarding the computation and presentation of rate of return information and other disclosures concerning past performance of accounts over which the CTA has had trading authority.[4] No final action was taken at that time. Now, due to the passage of time, intervening legislative and other developments, including reevaluation of certain of the issues involved, the Commission is reproposing these amendments.

## II. Proposed Amendments to Commission Regulations 4.25, 4.33, 4.34 and 4.35

### *A. Rate of Return Computation*

This proposal addresses how to measure advisors' rates of return in a margin- and leverage-based industry. From the CTA's perspective, trading is the same for all accounts in a program, regardless of the amount of actual funds. The use of margin, however, allows clients to fund accounts with much less in actual funds than the account size that they have agreed to have the CTA trade. Determination of the amount a client deposits with an FCM is between the FCM and the client—the CTA is not part of this decision, nor does it affect the CTA's level of trading for the client's account. Each existing CTA client will receive from its FCM reports of the amount of actual funds in the account, the profits or losses that occur, fees charged, and notice of any margin calls that may be necessary.

The rules that the Commission is proposing to revise apply to the disclosure of the CTA's past performance to prospective clients. The difficulty in basing such performance on actual funding levels arises primarily from the use of margin, which permits actual funding levels that may be so minimal as to make a return calculated on that basis greatly distorted. In addition, clients generally may open accounts with an FCM of their own choosing and clients in the same trading program may, in fact, have widely divergent amounts of actual funds supporting the same level of trading. In order to allow CTAs to present to prospective clients composite performance results that will be consistent for the accounts within the program, the Commission is proposing that the basis for the rate of return calculation be the amount on which the CTA is making its trading decisions—the nominal account size.

#### 1. Brief History of Methods Used To Compute Rates of Return

The Commission first required disclosure of the past performance of CTAs in 1981.[5] The rate of return for a period for a particular trading program was defined as the net performance [6] for that period divided by the net asset value at the beginning of the period.[7] At that time, the practice of partial funding was not common; clients generally deposited in their accounts with FCMs an amount equal to the amount that the CTA and its customer had agreed would determine the level of trading, which subsequently became known as the ''Nominal Account Size.''

In later years, Commission staff became aware that some CTA clients were not depositing the full nominal account size in their FCM accounts. This led the Division of Trading and Markets [8] to issue Advisory 87–2, which stated that only funds under the control of the CTA (''Actual Funds'') could be included in beginning net asset value (''BNAV'').[9] Advisory 87–2 stated that ''funds which the client has promised orally to provide upon request'' (there described as ''notional'' funds) could not be included in BNAV.

After Advisory 87–2 was issued, Commission staff were frequently apprised by industry participants of their concerns regarding the possible distortions to rates of return calculated based on actual funds rather than the account size, designated by the client, upon which the CTA made its trading decisions.[10] In 1993, the Commission issued Advisory 93–13, in an effort to alleviate these concerns and to reach a compromise between the actual funds and the ''notional'' funds methods of computing performance.[11]

Advisory 93–13 permitted CTAs to disclose, as their past performance, the

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[1] Commission rules cited herein are found at 17 CFR Ch. I (2002).

[2] Commission Rule 1.33 sets forth the requirements applicable to futures commission merchants (''FCMs'') with respect to reporting to their customers. Commission rules cited herein are found at 17 CFR Ch. I (2002).

[3] See 64 FR 41843 (August 2, 1999).

[4] Those proposed amendments developed out of rules proposed by National Futures Association (''NFA'') to permit CTAs to disclose past performance as computed on the basis of the client's nominal account size (the amount upon which the CTA bases its trading), rather than on the basis of the actual funds the client has placed in accounts subject to the CTA's control. The NFA proposal was also the subject of a concept release published by the Commission in June 1998 that discussed a number of possible enhancements and alternatives to the NFA proposal and sought public comment on those issues. See 63 FR 33297 (June 18, 1998).

[5] See 46 FR 26005, 26009 (May 8, 1981). Pursuant to the original Part 4 disclosure rules adopted in 1979, CTAs were permitted, but not required, to disclose their past performance in accordance with the format specified for commodity pool performance. 44 FR 1918, 1923 (January 8, 1979).

[6] Commission Rule 4.35(a)(6)(i)(D) currently specifies that net performance represents the change in the net asset value net of additions, withdrawals, redemptions, fees and expenses. Commission Rule 4.10(b) currently defines ''net asset value'' as ''total assets minus total liabilities, determined in accord with generally accepted accounting principles, with each position in a commodity interest accounted for at fair market value.''

[7] Commission Rule 4.35(a)(6)(i)(A).

[8] Following the Commission's reorganization in July 2001, the Division of Trading and Markets' role with respect to CPOs and CTAs is now carried out by the Division of Clearing and Intermediary Oversight.

[9] CFTC Advisory 87–2 [1986–87 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 23,624 (June 2, 1987). Advisory 87–2 specified that funds contained in a commodity trading account over which the CTA has been given trading authority must be included in BNAV, and set forth the conditions under which funds contained in any other type of account carried with the FCM could be included in BNAV.

[10] These concerns were among the issues addressed by the Managed Futures Subcommittee of the Commission's Regulatory Coordination Advisory Committee, which existed from 1990 to 1995.

[11] CFTC Advisory 93–13, 58 FR 8226 (February 12, 1993). The term ''nominal account size'' was introduced in Advisory 93–13.

rate of return of a ''fully-funded subset'' of their accounts, provided that two standards were met.[12] The first standard required that the aggregate of the actual funds for the fully-funded accounts be at least ten percent of the aggregate of the nominal account sizes of the accounts included in the program. The second standard required that the gross trading profit ratio for the subset be ''materially the same'' as the gross trading profit ratio for the aggregate.[13] In other words, the performance of the subset had to be, in fact, representative of the performance of the aggregate, considered on the basis of the nominal account sizes.

For example, if the CTA had 15 accounts, three of which were fully funded, the CTA could treat the rate of return of the three fully-funded accounts as representative of all 15 accounts as long as the two tests were met. Thus, if all 15 accounts had nominal account sizes of $100,000, the first standard would be met by the three fully-funded accounts—*i.e.*, $300,000/$1,500,000 is twenty percent, which exceeds the ten percent minimum. This test could also be met by one sufficiently large fully-funded account. If each of the 15 accounts experienced gross profits of $10,000, the gross trading profits ratio of the subset would be the same as the gross trading profits ratio of the aggregate, meeting the second test. Advisory 93–13 explicitly permitted a number of adjustments and exceptions to these two standards. For example, an account could use the fully-funded subset method despite failures to meet the ten percent test ''for a limited number of periods.''

Advisory 93–13 ameliorated disclosure problems for those CTAs that had sufficiently fully-funded accounts to meet the ten percent test. Commission staff nonetheless have increasingly encountered circumstances where CTAs have lacked (or lost) sufficient fully-funded accounts, but where disclosure based on actual funds levels would be misleading or confusing.

2. Proposed Changes to Commission Regulation 4.35(a)(6)(i) To Adopt Nominal Account Size as the Denominator in the Rate of Return Calculation

Existing Commission Regulation 4.35(a)(6)(i) requires that, in presenting past performance to prospective participants, the rate of return for a period be calculated by dividing net performance by the beginning net asset value. The proposed amendment to Regulation 4.35(a)(6)(i) would require that the rate of return be computed by dividing net performance by the nominal account size at the beginning of the period.[14] It is the proposed change in the denominator of the rate of return computation—from net asset value to nominal account size—that underlies the framework for performance presentation set forth in the rule proposal.

The Commission recognizes that each of the methods that has been used or proposed–the actual funds method, the fully-funded subset method, and the nominal account size method—has flaws. For example, under the actual funds method, two accounts with the same nominal account size, which hold the same market positions and number of contracts, and which experience the same gains or losses, would show different performance if the clients choose to fund their accounts differently.[15] Further, the CTA's presentation of its past performance for accounts in the same trading program could combine, in the same actual funds-based performance table, accounts with vastly different amounts of actual funds in relation to their nominal size.[16] The resulting composite presentation would blend the results of these accounts into a rate of return that would not be representative of any client's actual results. Some might argue that if the actual funds-based returns of these varyingly funded accounts differed materially from each other, their performance should be presented in separate tables.[17] This could result in numerous performance tables for each of the CTA's programs, overwhelming clients with excessive amounts of data and severely impeding the usefulness of the performance disclosure.

The fully-funded subset method has turned out to be unworkable for a number of reasons. The primary reason is that many CTAs lack fully-funded accounts. Although Advisory 93–13 allows for limited periods during which the fully-funded subset requirement is not met, this allowance is predicated on the anticipated resumption of the fully-funded subset in the near future. The Division has received numerous questions over the years from CTAs who have qualified for the fully-funded subset method for a period of time, but due to the closing of fully-funded accounts and inability to obtain new fully-funded accounts, cannot continue to use the fully-funded subset method.

Further, in recent years, the use of ''master accounts'' by commodity pools and clients who allocate to multiple CTAs has greatly increased. A master account is a central account in which a client deposits funds with the FCM to support trading done by several CTAs. Each of the CTAs is given trading authority for a sub-account, which will reflect the positions implemented by that CTA, and profits and losses on these positions, but to which no funds will be deposited. The margin requirements for these positions will be met by funds maintained in the master account. Although the CTA will know the nominal account size, the actual funds reported to the CTA will include only the value of the positions held in the sub-account (which could, in fact, be a negative amount due to unrealized losses). While in the past staff have permitted the allocation of funds in a master account to various CTAs to be computed and reported pursuant to a Liquid Asset Allocation (''LAA'') method,[18] LAA methods have not proven to be workable for the majority of CPOs and other clients with master accounts. Further, it is unclear that such

[12] ''Fully-funded'' refers to an account where the amount of Actual Funds equals the nominal account size.

[13] Advisory 93–13 included a specific definition of ''materially the same'' in the context of comparing two percentages, depending on the individual size of the two percentages (*i.e.*, 5 percent or less, between 5 percent and 10 percent, or 10 percent or more) and the difference between the two percentages. See 58 FR at 8229.

[14] Additional changes to Rule 4.35(a)(6)(i)(A)–(F) have been proposed to accommodate the use of nominal account size. These changes will be discussed further below.

[15] For example, Client A and Client B each have a nominal account size of $100,000. The CTA treats the two accounts identically, trading two S&P 500 futures contracts for each account. Each account experiences a $10,000 profit. Client A deposits $25,000 in actual funds, while Client B fully funds the account with $100,000. Using the actual funds method, Client A's rate of return would be 40%, and Client B's rate of return would be 10%, even though each client has the same nominal account size, has been traded identically, and has received the same dollar amount in profits.

[16] In practice, prior to the issuance of Advisory 93–13, Division of Trading and Markets staff interpreted the actual funds method to require one composite table that was based solely on actual funds, and to permit a supplemental table including ''notional funds'' (57 FR 53457, 53459 (November 10, 1992). This interpretation appears to have been based on provisions regarding retroactive application of Advisory 87–2, as described in an Addendum to CFTC Advisory 87–2 ([1986–87 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 23,759 (August 12, 1987)).

[17] Rule 4.35(a)(3)(ii) specifies that accounts whose rates of return differ materially from each other may not be presented in the same composite.

[18] See CFTC Interpretative Letter 88–1, ''Application of Division of Trading and Markets Advisory 87–2,'' [1987–1990 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶24058 at 34639–40 (December 16, 1987).

allocation provides insight into the return based on ''actual'' funds.

3. Objections to the Nominal Account Size Method Addressed

Concerns have been raised that CTAs might manipulate their nominal account sizes.[19] A CTA that can establish nominal account sizes without being required to find customers willing to fully fund accounts at such sizes might be unrestrained in setting the nominal account size, and thus could minimize the apparent size of losses and smooth the apparent volatility of its trading over time. Increasing the nominal account size to minimize the apparent size of losses, however, will unavoidably have the effect of minimizing the apparent size of gains. CTAs will thus be faced with countervailing incentives. Some have noted a converse problem posed by the existing rules: futures and derivatives positions can be taken by depositing very small amounts of actual funds for margin, relative to the value of the contract. Positive rates of return computed on the basis of a relatively small amount of actual funds in accounts whose level of trading is based on a much greater nominal account size would be magnified and could provide a potentially misleading measure of the CTA's success. As NFA's comment letter on the earlier rule amendment proposal observed, in its experience, ''* * * unwary customers are more likely to be lured into the futures markets by allusions to large profits than by information implying that futures trading is a conservative investment.'' The Commission's own experience in this area has been similar, and it has no basis to believe that this proposal creates any additional incentives for CTAs to set unreasonable nominal account sizes.

Some have stated that using nominal account size to compute rates of return would create an appearance of lowered volatility and that disclosure of volatility experienced by program participants would be undermined if nominal account size were used to compute rates of return. But the rules proposed in this release are no more likely to mask volatility than the fully-funded subset method permitted since 1993. The funding level—full or partial—chosen by past participants neither helps nor harms prospective participants who will be receiving past performance data based on nominal account size. A prospective participant who chooses to partially fund will experience volatility magnified by his or her partial funding level, and will not be helped by the fact that other participants chose to fully fund in the past. Conversely, a prospective participant who chooses to fully fund will experience volatility corresponding to the nominal account size, and will not be harmed by the fact that other participants chose to partially fund in the past. Moreover, the performance table will contain a pointed numerical example of the effect of partial funding on volatility in the context of worst monthly and peak-to-valley draw-downs. This example–based either on the lowest actual funding level or a straight 20% funding level—will demonstrate the enhanced volatility of partially funded accounts in a form calculated to draw the participant's attention.

Investors should consider not only the ''cash they must put up'' initially, but the losses to which they are exposed. In this context, participation in managed futures accounts is far different from investment in stocks, real estate, or even commodity pools. As has been noted: ''Commodity trading intrinsically involves leverage, the only purchase is a futures contract (not the actual asset) and the amount of cash required is artificially determined by exchange rules, broker policies, CTA negotiated agreements and regulatory requirements and can change day by day.''[20]

Investments in stock, real estate, or collective investment vehicles such as mutual funds or commodity pools can be quantified in advance, even if purchased on margin or through other borrowing. An investor can purchase 100 shares of Example Co., Inc. (or Example Fund, Inc.) at $50 a share for $5,000. Even if these shares are purchased on margin, $5,000 is generally the limit of the loss to which the investor is exposed.[21] This relative certainty is absent in the context of futures. A managed futures account participant who enters into, for example, a stock index futures contract gains (or loses) the change in value of the collection of stocks. The participant must post margin, but the margin does not represent the limit of the participant's liability. If the participant's losses exceed the initial margin, the participant will owe the excess. Commission Rule 4.34(b) requires that CTAs disclose these facts to prospective clients, and a CTA which encouraged participants to think of the ''cash they have put up'' as the limit of their losses could run afoul of Section 4*o* of the Commodity Exchange Act (the ''Act'').[22]

To be sure, the Commission has observed that there is no standard among CTAs for the setting of nominal account sizes.[23] The Commission does not intend to impose a standard for the setting of nominal account sizes on CTAs. The proposed rule does require that the CTA disclose the factors it considers in determining the level of trading for a given nominal account size in the offered trading program and an explanation of how those factors are applied. Moreover, adopting nominal account size as the denominator for the rate of return calculation would provide a uniform basis for all CTAs to present rate of return, which does not exist under the reporting scheme that has been in effect since the adoption of Advisory 93–13. Use of nominal account size would permit a much more meaningful comparison of the performance results of CTAs.

After consideration of the benefits and drawbacks of each of these methods of calculating CTAs' rates of return, the Commission is proposing the nominal account size method, coupled with a framework of documentation and disclosure requirements, as the method that best reflects the reality of how managed accounts are traded, including information regarding volatility and draw-downs. As discussed more fully below, the existence of a written agreement that documents the nominal account size in advance of the CTA's trading for the account is a critical component of the performance calculation and reporting scheme the Commission is proposing.

*B. Documentation of Nominal Account Size*

The proposed rules would add new paragraph (c) to Rule 4.33 to require documentation of the nominal account size agreed upon by the CTA and client, as well as other terms applicable to the CTA's trading for the client's account. This provision would require that the CTA execute a written agreement with each client that specifies: The nominal account size; the name or description of the trading program in which the client is participating; the basis for the computation of fees; how additions or withdrawals of actual funds, or profits and losses will affect each of (a) the nominal account size and (b) the computation of fees; and whether the client will fully or partially fund the

[19] See, *e.g.*, ''Proposed Rule Could Help Mask Commodity Trading Volatility,'' New York Times, September 2, 1999; and ''Commodity-Adviser Reporting Rule May Change,'' Wall Street Journal, September 7, 1999.

[20] Arthur F. Bell, Jr. & Associates commenting on the earlier rule amendment proposal.

[21] Transaction fees and interest are being ignored for the purposes of these examples.

[22] 7 U.S.C. 6*o* (2000).

[23] See 63 FR 33297 (June 18, 1998).

account. The requirement that the nominal account size must be documented in advance of the CTA's trading for the client's account will also minimize the possibility that CTAs will manipulate their returns to appear either less volatile or more positive by frequent adjustment of their nominal account sizes, particularly since any revision to the nominal account size must be documented in a new agreement, or an addendum to the existing agreement, signed by the client.

The Commission believes that documentation of the agreement between CTAs and their clients is important, even if all the CTA's client accounts are fully-funded, and therefore the proposed requirements of Rule 4.33(c) would apply to CTAs whether or not they accept partially funded accounts. As the proposed rule indicates, CTAs would not need to use a separate agreement to respond to the requirements specified in Rule 4.33(c), but could incorporate the requirements into their existing client agreements.

In addition, Rule 4.33(c) would require that changes to nominal account size, other than those explicitly provided for in the existing agreement (*e.g.*, the effect of gains/losses), must be in writing, must be signed by the client, and must explicitly indicate the current date, the change in the nominal account size and the effective date of that change.[24] This requirement could be met by a simple one-sentence note from the client requesting the change in nominal account size and including the dollar amount of the new nominal account size, the effective date of the change, the signature and typed or printed name of the client, and the date the request was signed.[25]

*C. Changes to Definitions*

The Commission proposed revisions to Rule 4.10(l) to accommodate use of nominal account size as the denominator in the calculation of the peak-to-valley draw-down figures.[26] Additional changes are being proposed to codify definitions of nominal account size (Rule 4.10(m)), actual funds (Rule 4.10(n)), partially-funded account (Rule 4.10(o)) and most recent five years (4.10(p)).

The Commission wishes to make clear that Advisories 87–2 and 93–13, as well as Interpretative Letter 88–1, would be, on a prospective basis, superseded in their entirety by the proposed rules or any final rules resulting from this rulemaking. Questions have been raised about the continuing applicability of the quantitative materiality standard that was established in Advisory 93–13 to determine whether a CTA's accounts qualified for use of the fully-funded subset method. Although Advisory 93–13 clearly stated that the standard was intended to be applicable only in the context of the Advisory, the Commission understands that these standards have come to be relied on more broadly in ascertaining compliance with composite performance requirements of Rule 4.35(a)(3). The Commission would accept those standards as guidance, but not to the exclusion of other approaches that may fall outside the threshold of Advisory 93–13. Registrants should continue to consider all relevant facts and circumstances in making determinations regarding materiality.

*D. Disclosure of Actual Funding Levels and Funds Under Management*

The Commission believes that it would be misleading to describe ''notional funds,'' which the client has chosen not to place in an account over which the CTA has trading authority, as ''funds under management.'' The proposed revisions to Rule 4.35(a)(1)(iv), therefore, would clarify that the disclosure of funds under management must reflect only the actual funds committed to the CTA's trading program rather than the aggregate of nominal account sizes.

The Commission's proposed adoption of nominal account size for purposes of computing the CTA's trading program rate of return is not intended to eliminate the distinction between actual funds and nominal account size. As we have noted before, nominal account size is not a commitment of actual funds to the CTA's control, nor does it represent the maximum amount of the client's potential losses or of the client's obligations to the FCM. The Commission continues to believe that knowledge of the amount of funds that a CTA's clients have been willing to entrust to the control of the CTA, or the fact that the CTA does not possess such information, may be considered valuable by prospective clients. In addition, CTAs would not be precluded from disclosing the aggregate of nominal account sizes, and in fact may choose to present such information in their performance capsules adjacent to the disclosure of actual funds under management (See proposed Rule 4.35(a)(1)(ix)(D)). Therefore, the Commission is proposing revisions to Rule 4.35(a)(1)(iv).

To accommodate those situations where CTAs do not have access to information regarding clients' actual funds, proposed Rule 4.35(a)(1)(iv) would permit a CTA simply to make a statement of the fact that it does not have sufficient information regarding the funding of its clients' accounts to determine the aggregate of actual funds committed to its programs. Cases involving the use of master accounts, or other funding arrangements between the client and FCM, that preclude the CTA from having access to information regarding the client's actual funds, might lead CTAs to state that they do not know the amount of actual funds. The representation by the CTA of its lack of knowledge of this amount will provide clients with valuable information regarding the extent to which they may rely on that factor. The CTA would continue to be required to maintain the documentation on which its performance presentation is based[27] and such documentation should be sufficient to support the information in the performance capsule regarding the disclosure, if any, of actual funds under management.

*E. Disclosures Regarding Partial Funding of Accounts*

Proposed Rule 4.34(p) would require disclosure to prospective clients of material information concerning the practice of partially funding an account and the factors considered by the CTA in determining the trading level for a given nominal account size. The discussion would be required to include: (1) How the management fees would be computed, expressed as a percentage of the nominal account size, and an explanation of the effect of partially funding an account on the management fees as a percentage of actual funds; (2) an estimated range of the commissions generally charged to an account expressed as a percentage of the nominal account size and an explanation of the effect of partially funding an account on the commissions as a percentage of actual funds; (3) a statement that partial funding increases leverage, that leverage will magnify both

[24] The effective date would be on or after the date that the change is made.

[25] Commission Rule 1.4 permits use of electronic signatures with respect to compliance with Commission rules that require a document to be signed by a customer, participant or client. An electronic signature could therefore be used for the agreement required by Rule 4.33(c), in accordance with the provisions of Rule 1.4 (*i.e.*, that the electronic signature complies with applicable Federal laws and other Commission rules, and that the CTA must adopt and utilize reasonable safeguards regarding the use of electronic signatures).

[26] Rule 4.10(k) defines ''draw-down'' as ''losses experienced by a pool or account over a specified period.'' Since the definition in Rule 4.10(k) does not refer to a method for computing such losses, no revision to this definition would be necessary.

[27] See Rules 4.33(a) and 4.35(a)(6)(ii).

positive and negative rates of return, and that the greater the disparity between the nominal account size and the amount deposited, maintained or made accessible to the FCM, the greater the likelihood and frequency of margin calls, and the greater the size of margin calls as a percentage of the amount of actual funds committed to the commodity trading advisor's program; and (4) a description of the factors considered by the CTA in determining the level of trading for a given nominal account size in the offered trading program and an explanation of how those factors are applied.

*F. Disclosures Concerning Draw-down*

1. Disclosure of Draw-Down at the Lowest Funding Level

Proposed Rule 4.35(a)(1)(ix)(A) would require CTAs who accept partially-funded accounts to present draw-down figures computed on the basis of the actual funds committed to the CTA's program by the client with the lowest ratio of actual funds to nominal account size in the trading program.[28] If the CTA did not have sufficient information regarding the funding level of its client accounts, or if the lowest ratio was zero, the draw-down information would be presented at a funding level of 20 percent. These additional draw-down figures would be presented adjacent to the worst monthly and peak-to-valley draw-down percentages based on the aggregate nominal account sizes.

If a client funds its account traded by the CTA at a level of actual funds that is less than the nominal account size, then gains or losses will represent a larger percentage of the client's actual funds. Further, the smaller the amount of actual funds is in relation to the nominal account size, the faster losses will reduce the amount of actual funds, increasing both the likelihood of margin calls and the amount of additional margin that may be required. The purpose of disclosing draw-downs at the least-funded level is to highlight these effects to prospective clients who may be considering partially funding their accounts with the CTA. The option of using a 20% level is intended to accommodate situations where the CTA does not have sufficient information regarding the funding level of its client accounts, or where the lowest funding ratio is zero, precluding calculation of a meaningful number.

Proposed Rule 4.35(a)(1)(ix)(A) would require the addition of only two percentage draw-down figures, adjacent to the worst monthly and peak-to-valley draw-down percentages for the aggregate nominal account sizes. This would not amount to data overload. Further, since the intent of the disclosure is to convey the impact of draw-downs on the actual funds in partially-funded accounts, use of the 20% funding level where CTAs do not have any accounts with actual funding or do not know the amount of actual funds would enable their performance capsules to convey information about the increased impact of draw-downs on the actual funds in partially-funded accounts.

2. Use of Composite Draw-down

Proposed Rules 4.35(a)(1)(v) and (vi) would require that the worst monthly and peak-to-valley draw-down amounts be based on the aggregate of nominal account sizes, *i.e.*, the composite of accounts, rather than the worst individual account.[29] A variety of factors, including, but not limited to, differences due to trade execution, fees, commissions, and the timing of opening or closing accounts, may have an impact on the returns for individual accounts. The effect of these factors must be considered by the CTA in the development of its composite performance tables and any material differences among the accounts in the composite must be discussed.[30] For a performance table that complies with the Commission's rules on use of composites, disclosure of draw-down information on a composite basis would not be misleading. However, CTAs would remain subject to the requirement of Rule 4.34(o) to disclose all material information to existing or prospective clients even if such information is not specifically required by these regulations.

*G. Treatment of Interest Income*

The proposed definition of net performance in Rules 4.10(*l*)(3) and 4.35(a)(6)(i)(B)[31] would permit CTAs to include interest income on funds deposited in the client's commodity interest account directed by the CTA, as well as any other income on positions held as part of the CTA's program. The fact that trading fees are charged against the CTA's performance, even where the commission rate is negotiated by the client and the FCM, supports the inclusion of interest earned at the FCM in the CTA's performance to maintain parity. In addition, interest is, in a real sense, part of the return on the funds. Regardless of the amount of actual funds a client deposits with the FCM, whether influenced by the CTA's trading strategies, the FCM's credit determination, or the client's wishes, income on these funds is part of the account's performance. Further, the computation of net performance under the regulations that have been in effect since 1981 has included interest income. The components of net performance—the numerator of the rate of return computation—will not be affected by the change of the denominator from net asset value to nominal account size. It is the adoption of nominal account size, rather than net asset value, as the basis for performance calculation that will require changes to the definition of net performance in proposed Rules 4.10(l)(3) and 4.35(a)(6)(i)(B).

The proposed rule also would provide that no interest income may be imputed with respect to nominal account sizes or otherwise computed on a pro-forma basis. The Commission notes that the reference in the proposed rules to ''other income'' on instruments held as part of the CTA's program is intended to apply to programs in which the CTA may direct the trading of instruments, such as stocks or bonds, on which income is earned.[32] While this provision may not be applicable to most CTAs, it is intended to permit those CTAs who direct the trading of income-producing

[28] For example, if the lowest funding level is 25 percent and the greatest monthly draw-down is 15 percent, the draw-down shown on the basis of actual funding would be 60 percent (15 percent ÷ 25 percent).

[29] Current Rule 4.10(k) defines the term ''Draw-down as ''losses experienced by a pool or account over a specified period: Rule 4.10(l) defines the term ''Worst peak-to-valley draw-down'' for a pool, account or trading program. In its adopting release for the most recent revisions to the Part 4 rules, the Commission noted that '' . . . the draw-down figures in a composite in a CTA Disclosure Documents are the worst experienced by *any one of the accounts* included in the composite'' (emphasis added). 60 FR 38146, 38162 (July 25, 1995).

[30] Rule 4.35(a)(3) states:

(i) Unless such presentation would be misleading, the performance of accounts traded pursuant to the same trading program may be presented in composite form on a program-by-program basis * * *.

(ii) Accounts that differ materially with respect to rate of return may not be presented in the same composite.

(iii) The commodity trading advisor must discuss all material differences among the accounts included in a composite.

[31] Although net performance is defined in the context of both Rule 4.10(*l*), with respect to computation of worst peak-to-valley draw-down, and Rule 4.35(a)(6)(i)(B), with respect to calculation of performance information, the definitions are the same.

[32] While this provision acknowledges that CTAs may offer programs that trade instruments in addition to futures contracts, it in no way implies that such activity may be conducted by CTAs outside of the appropriate registration or other regulatory requirements of agencies with jurisdiction over those instruments.

instruments as part of their trading programs to reflect the performance of those instruments in their trading results. In the disclosure document review process and compliance audits, close attention would be paid to the description of the trading program and other documentation regarding the CTA's direction of income-producing instruments included in its performance record.

*H. Range of Rates of Return for Closed Accounts*

The Commission proposes to revise Rule 4.35(a)(1)(viii) to require that the performance capsule for the offered program include, in addition to the number of accounts closed with profits and the number closed with losses, the range of rates of return for the accounts closed with net lifetime profits and accounts closed with net lifetime losses, during the five-year period. The Commission believes that disclosing the range of rates of return for closed accounts in the offered program provides important summary information on the variation in returns experienced by individual clients and will be useful to prospective clients considering participation in the CTA's program. Because the draw-down information under the revised rules will be presented on a composite basis, presentation of the range of rates of return for closed accounts provides valuable information on the results experienced by individual clients.

The Commission notes that under the proposed rule amendments, both the numbers of accounts closed with positive versus negative rates of return, as well as the ranges of rates of return for accounts in each category, must be disclosed only for those accounts that both opened and closed within the required five-year and year-to-date time period. The Commission does not believe that this change will diminish the disclosure of material information to prospective clients, because of the tendency of clients to quickly close accounts that experience large losses. Accounts that experienced strongly negative returns before the five-year time period are likely to have been closed before the end of that time period, and losses experienced as a result of the offered program during the five-year period are likely to have been experienced by an account that both opened and closed during that period. The Commission wishes to make clear that any additional information that the CTA believes is necessary to explain the circumstances affecting the ranges of returns presented in the performance capsule may be provided, pursuant to existing rules regarding supplemental disclosures and material information.[33]

*I. Treatment of Additions and Withdrawals in Computing Rate of Return*

In proposing to amend Rule 4.35(a)(6)(i)(B), the Commission notes that CTAs would be permitted to choose, for their rate of return computation, one of the following three methods: (1) Net performance divided by beginning nominal account size; (2) daily compounded rate of return; or (3) net performance divided by the average weighted nominal account sizes for the month. These proposed changes would incorporate alternative methods of computing rate of return to account for intramonth additions and withdrawals, as permitted by the CFTC's 1991 Advisory.[34] The Commission is not proposing to include the Only Accounts Traded Method as an option CTAs may choose prospectively due to concerns that it allows for accounts to be excluded entirely from the rate of return computation. The Commission will, however, carefully consider proposals regarding any alternative method of addressing the effect of additions and withdrawals on the rate of return computation, whether as part of this rulemaking proposal or otherwise in the future.

The rule changes proposed herein would supersede applicability to CTAs of the CFTC's 1991 Advisory.[35] CTA performance computed in accordance with any of the alternative methods described in the 1991 Advisory for periods prior to the date upon which the rule changes proposed herein become effective, however, would not need to be revised. Because commodity pool performance may only be reported on the basis of actual funds, applicability of the 1991 Advisory to CPOs reporting commodity pool performance would be unchanged.

*J. Disclosure of CTA Performance in CPO Disclosure Documents*

The Commission is proposing changes to the presentation of CTA performance in CPO disclosure documents primarily to conform such presentation with the proposed revisions to Rule 4.35(a)(1). The Commission emphasizes that narrative disclosure of the pool's allocations to its CTAs, as well as the use of leverage in determining such allocations, continues to be required pursuant to existing Rules 4.24(g) and 4.24(h).

**III. Transitional Provisions**

The Commission proposes to require CTAs and CPOs to comply with the revisions proposed herein, including the requirement to obtain the documentation required by new Rule 4.33(c) for both new and existing clients, by no later than the beginning of the calendar quarter that is at least 90 days after the date of publication of the final rules. The Commission seeks comment on any difficulties anticipated in complying with these proposed requirements by that date. CTAs and CPOs would be permitted to adopt these changes immediately upon the effective date of the final rules as adopted.

**IV. Request for Comments Regarding a Core Principle Alternative**

The Commission has received a number of requests from the managed funds industry that Commission policy pertaining to CTA disclosure of past performance to prospective clients be made consistent with the approach undertaken in the securities industry.[36] Under Federal securities laws there are no rules that mandate the manner in which investment advisers disclose past performance. Generally, investment advisers may present past performance in any manner that does not run afoul of general anti-fraud provisions.[37] It has been suggested that the Commission adopt a core principle in order to achieve parity with applicable securities laws and regulations as they relate to the disclosure of past performance made by CTAs to prospective clients.[38] Such a core principle would permit CTAs to present past performance to prospective clients in any manner they choose so long as such information is offered in a manner that is factual and balanced and is not misleading or fraudulent.

Consistent with the intention of the Commodity Futures Modernization Act

[33] *See,* Commission Rules 4.34(n) and 4.34(o).

[34] CFTC Advisory, ''Adjustments for Additions and Withdrawals to Computation of Rate of Return in Performance Records of Commodity Pool Operators and Commodity Trading Advisors,'' 56 FR 8109 (February 27, 1991).

[35] CFTC Advisory, ''Adjustments for Additions and Withdrawals to Computation of Rate of Return in Performance Records of Commodity Pool Operators and Commodity Trading Advisors,'' 56 FR 8109 (February 27, 1991).

[36] *See* Transcript from CFTC Roundtable on Managed Funds Issues <*http://www.cftc.gov/files/opa/press02/oparoundtable091902.pdf*>.

[37] *See* the Investment Advisers Act of 1940 section 206(4) (15 U.S.C. 80b–6(4)) and Securities and Exchange Commission Rule 275.206(4)–1(a)(5) (17 CFR 275.206(4)–(1)(a)(5)). For a more complete discussion regarding the use of past performance by investment advisers for soliciting clients, *see* Robert J. Zutz, *Compliance Review,* Schwab Institutional, Vol. 10, Issue 8, Aug. 2001.

[38] *See,* e.g., Testimony of George Crapple at the CFTC Roundtable on Managed Funds Issues. Transcript from CFTC Roundtable on Managed Funds Issues at 84.

of 2000,[39] the Commission is requesting comment on the desirability of implementing a core principle that would replace the current rules, and ameliorate the need for the amendments proposed herein, regarding the manner in which a CTA presents past performance to prospective clients. In particular, the Commission is requesting comments on the following questions:

(1) What form should such core principle take? Commenters are requested to provide specific language for the core principle.

(2) Should certain presentations of past performance be specifically prohibited or limited?

(3) Should the rules proposed herein serve as a safe harbor in the event the Commission determines to adopt a core principle approach, and/or should the Commission develop more general guidance concerning compliance with the core principle?

(4) Would the implementation of a core principle approach lead to more or less meaningful and useful information being provided to prospective clients?

(5) Is the experience of the securities industry with the use of a core principle approach for performance presentation relevant to the use of such an approach in the futures industry?

In offering the above questions, the Commission does not intend to limit the scope of the discussion regarding the alternative of a core principle. These questions are meant only as a starting point and the Commission encourages the submission of comments that address these, as well as any other pertinent questions.

## V. Related Matters

### *A. Regulatory Flexibility Act*

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–611 (1994), requires that agencies, in proposing rules, consider the impact of those rules on small businesses. The Commission has previously established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its rules on such entities in accordance with the RFA.[40] The Commission previously has determined that registered CPOs are not small entities for the purpose of the RFA.[41] With respect to CTAs, the Commission has stated that it would evaluate within the context of a particular rule proposal whether all or some affected CTAs would be considered to be small entities and, if so, the economic impact on them of any rule.[42] In this regard, the Commission notes that the rule revisions adopted herein create some changes to the content of the documentation and disclosure requirements for CTAs, but do not increase such requirements, and, in fact, are expected ultimately to ease the computational and recordkeeping requirements for CTAs who manage partially-funded client accounts. The Commission has previously determined that the disclosure requirements governing this category of registrant will not have a significant economic impact on a substantial number of small entities.[43] Therefore, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that these regulations will not have a significant economic impact on a substantial number of small entities.

### *B. Paperwork Reduction Act*

These rules [Sections 4.31 and 4.33] contain information collection requirements. As required by the Paperwork Reduction Act of 1995,[44] the Commission has submitted a copy of this rule to the Office of Management and Budget (OMB) for its review.[45]

Collection of Information

Rules relating to the operations and activities of Commodity Pool Operators and Commodity Trading Advisors and to monthly reporting by Futures Commission Merchants, OMB control number 3038–0005.

The proposed amendments would not affect the paperwork burdens associated with the above collections of information, which have previously been approved by OMB in connection with the Commission's previous submission of the proposed rules.

Copies of the information collection submission to OMB are available from the CFTC Clearance Officer, 1155 21st Street, NW., Washington, DC 20581, (202) 418–5160.

Persons wishing to comment on the information collection requirements that would be required by these proposed rules should contact the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Desk Officer for the Commodity Futures Trading Commission.

The Commission considers comments by the public on this proposed collection of information in—

Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;

Evaluating the accuracy of the Commission's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;

Enhancing the quality, utility, and clarity of the information to be collected; and

Minimizing the burden of the collection of the 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 submissions of responses.

OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to the Commission on the proposed regulations.

Copies of the information collection submission to OMB are available from the CFTC Clearance Officer, 1155 21st Street, NW., Washington, DC 20581 (202) 418–5160.

## List of Subjects in 17 CFR Part 4

Brokers, Commodity futures, Commodity pool operators, Commodity trading advisors.

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act and, in particular, sections 1a(4), 4k, 4*l*, 4m, 4n, 4*o* and 8a, 7 U.S.C. 1a(4), 6k, 6*l*, 6m, 6n, 6*o*, and 12a, the Commission hereby proposes to amend Chapter I of the Code of Federal Regulations as follows:

## PART 4—COMMODITY POOL OPERATORS AND COMMODITY TRADING ADVISORS

1. The authority citation for part 4 continues to read as follows:

**Authority** : 7 U.S.C. 1a, 2, 4, 6b, 6c, 6l, 6m, 6n, 6o, 12a and 23.

2. Section 4.10 is proposed to be amended by revising paragraph (l) and adding paragraphs (m), (n), (o) and (p) to read as follows:

### § 4.10 Definitions.

* * * * *

[39] Pub. L. No. 106–554, 114 Stat. 2763 (2000) (codified as amended in scattered sections of 7 U.S.C.). *See, e.g.*, section 125 (requiring the Commission to conduct a study of the Act and the Commission's rules and orders governing the conduct of registrants under the Act, identifying, among other things, Commission rules that may be replaced by core principles).

[40] 47 FR 18618–18621 (April 30, 1982).

[41] 47 FR 18619–18620.

[42] 47 FR 18618–18620.

[43] See 60 FR 38146, 38181 (July 25, 1995) and 48 FR 35248 (August 3, 1983).

[44] Pub. L. 104–13 (May 13, 1995).

[45] 44 U.S.C. 3504(h).

(l) *Worst peak-to-valley draw-down* means:

(1) For a commodity pool, the greatest cumulative percentage decline in month-end net asset value due to losses sustained during any period in which the initial month-end net asset value is not equaled or exceeded by a subsequent month-end net asset value. Such decline must be expressed as a percentage of the initial month-end net asset value, together with an indication of the months and year(s) of such decline from the initial month-end net asset value to the lowest month-end net asset value of such decline.

(2) For an account directed by a commodity trading advisor or for a commodity trading advisor's trading program, the greatest negative net performance during any period, beginning at the start of one month, and ending at the conclusion of that month or a subsequent month. The worst peak-to-valley draw-down must be expressed as a percentage of the nominal account size at the beginning of the period, together with an indication of the months and year(s) of such draw-down.

(3)(i) For purposes of paragraph (l)(2) of this section, net performance for a period is defined as the total of:

(A) The realized gain or loss on positions closed during the period; plus

(B) The change during the period in unrealized gain or loss; plus

(C) Interest income on funds on deposit in an account at a futures commission merchant to margin the client account which a commodity trading advisor directs; plus

(D) Other income earned on positions held as part of the commodity trading advisor's program; minus

(E) Fees and expenses.

(ii) No interest or other income may be imputed with respect to nominal account sizes or otherwise computed on a pro-forma basis.

(4) For purposes of §§ 4.25 and 4.35, a peak-to-valley draw-down, which began prior to the beginning of the most recent five calendar years and continues into or ends during the most recent five years, is deemed to have occurred during such five-calendar-year period.

(m) *Nominal account size* means the account size, designated in the written agreement specified in § 4.33(c), that establishes the client's level of trading in a commodity trading advisor's program.

(n) *Actual funds* means the amount of margin-qualifying assets, either:

(1) On deposit in an account at a futures commission merchant to margin the client account which a commodity trading advisor directs; or

(2) In another account, so long as the commodity trading advisor has written evidence demonstrating the following:

(i) The client owns the funds;

(ii) The futures commission merchant carrying the client's account that the commodity trading advisor directs (the ''trading account'') has the power readily to use all, or a designated portion of, the funds in the other account for the purpose of meeting margin requirements in connection with the trading account, on a routine operational basis and without advance notice to the client; and

(iii) The commodity trading advisor has ready access to information concerning the balance in the other account available to meet margin requirements for the trading account.

(o) *Partially-funded account* means a client participation in the program of a commodity trading advisor in which the amount of actual funds is less than the nominal account size.

(p) For purposes of §§ 4.25 and 4.35, the term most recent five years means:

(1) The time period beginning January 1 of the calendar year five years prior to the date of the Disclosure Document and ending as of the date of the Disclosure Document; or

(2) The life of the trading program, if less than five years.

3. Section 4.25(a)(1)(ii) is proposed to be amended by revising paragraphs (a)(1)(ii)(D)(1) and (2), (a)(1)(ii)(E) and (a)(1)(ii)(F) to read as follows:

**§ 4.25 Performance disclosures.**

(a) * * *

(1) * * *

(ii) * * *

(D)(1) The aggregate of actual funds for all of the trading programs of the trading advisor or other person trading the account, as of the date of the Disclosure Document or, if the commodity trading advisor does not have sufficient information regarding the funding of its clients' accounts to determine the aggregate of actual funds for its programs, a statement of that fact;

(2) The aggregate of actual funds for the specified trading program of the commodity trading advisor, as of the date of the Disclosure Document or, if the commodity trading advisor does not have sufficient information regarding the funding of its clients' accounts to determine the aggregate of actual funds for the specified trading program, a statement of that fact.

(E) The greatest monthly draw-down during the most recent five years for the trading program specified, expressed as a percentage of aggregate nominal account sizes, and indicating the month and year of the draw-down.

(F) The greatest peak-to-valley draw-down during the most recent five years for the trading program specified, expressed as a percentage of aggregate nominal account sizes at the beginning of the period, and indicating the month(s) and year(s) of the draw-down.

* * * * *

4. Section 4.33 is proposed to be amended by adding paragraphs (c) and (d) to read as follows:

**§ 4.33 Recordkeeping.**

* * * * *

(c) A commodity trading advisor must obtain a written agreement signed by each client which, at a minimum, clearly specifies:

(1) The nominal account size;

(2) The name or description of the trading program in which the client is participating;

(3) The basis for the computation of fees;

(4) How additions or withdrawals of actual funds, profits, and losses will each affect the nominal account size and the computation of fees; and

(5) Whether the client will fully or partially fund the account.

(d) Any changes to nominal account size (other than changes resulting from the factors listed in § 4.33(c)(4) and documented as required by that subsection) must be in writing, must be signed by the client, and must explicitly indicate the current date, the new nominal account size and the effective date of the change.

5. Section 4.34 is proposed to be amended by adding paragraph (p) to read as follows:

**§ 4.34 General disclosures required.**

* * * * *

(p) Additional Disclosure by Commodity Trading Advisors Accepting Partially-funded Accounts. A commodity trading advisor that accepts a partially-funded account (as defined in § 4.10(o)) must disclose:

(1) How the management fees will be computed, expressed as a percentage of the nominal account size, and an explanation of the effect of partially funding an account on the management fees as a percentage of actual funds;

(2) An estimated range of the commissions generally charged to an account expressed as a percentage of the nominal account size and an explanation of the effect of partially funding an account on the commissions as a percentage of actual funds;

(3) A statement that partial funding increases leverage, that leverage will magnify both positive and negative rates of return, and that the greater the disparity between the nominal account

size and the amount deposited, maintained or made accessible to the futures commission merchant, the greater the likelihood and frequency of margin calls, and the greater the size of margin calls as a percentage of the amount of actual funds committed to the commodity trading advisor's program; and

(4) A description of the factors considered by the commodity trading advisor in determining the level of trading for a given nominal account size in the offered trading program and an explanation of how those factors are applied.

6. Section 4.35 is proposed to be amended by revising paragraphs (a)(1)(iv) through (a)(1)(ix), (a)(2)(iv), (a)(6)(i)(A) through (F), and (a)(6)(ii) to read as follows:

**§ 4.35 Performance disclosures.**

* * * * *

(a) General principles.—(1) * * *

(iv)(A) The aggregate of actual funds for all of the trading programs of the trading advisor or other person trading the account, as of the date of the Disclosure Document, or, if the commodity trading advisor does not have sufficient information regarding the funding of its clients' accounts to determine the aggregate of actual funds for its programs, a statement of that fact;

(B) The aggregate of actual funds for the specified trading program of the commodity trading advisor, as of the date of the Disclosure Document, or, if the commodity trading advisor does not have sufficient information regarding the funding of its client accounts to determine the aggregate of actual funds for the specified trading program, a statement of that fact.

(v) The greatest monthly draw-down during the most recent five years for the trading program specified, expressed as a percentage of aggregate nominal account sizes, and indicating the month and year of the draw-down;

(vi) The greatest peak-to-valley draw-down during the most recent five years for the trading program specified, expressed as a percentage of aggregate nominal account sizes at the beginning of the period, and indicating the month(s) and year(s) of the draw-down;

(vii) Subject to § 4.35(a)(2) for the offered trading program, the annual and year-to-date rate-of-return for the program specified for each of the five most recent calendar years and year-to-date, computed on a compounded monthly basis; and

(viii) In the case of the offered trading program:

(A)(1) The number of accounts traded pursuant to the offered trading program that were opened and closed during the period specified in § 4.35(a)(5) with a positive net lifetime rate of return as of the date the account was closed; and

(2) The range of rates of return for accounts that were both opened and closed during the period specified in § 4.35(a)(5) and closed with positive net lifetime rates of return; and

(B)(1) The number of accounts traded pursuant to the offered trading program that were opened and closed during the period specified in § 4.35(a)(5) with negative net lifetime rates of return as of the date the account was closed; and

(2) The range of rates of return for accounts that were both opened and closed during the period specified in § 4.35(a)(5) and closed with negative net lifetime rates of return.

(C) The net lifetime rate of return shall be calculated as the compounded product of the monthly rates of return for each month the account is open.

(ix) In addition to the information specified in § 4.35(a)(1)(i)–(viii), where the commodity trading advisor accepts partially-funded accounts, the performance capsule must include:

(A) A statement that rates of return are based on nominal account size.

(B) In a column adjacent to the presentation of data based on nominal account size, the draw-down information required by § 4.35(a)(1)(v) and (vi), divided by the percentage of actual funds committed to the commodity trading advisor's program by the client with the lowest ratio of actual funds to nominal account size in the trading program.

(1) If the commodity trading advisor does not have sufficient information regarding the funding level of its client accounts to determine the lowest ratio, or if the lowest ratio is zero, present this information at a funding level of 20 percent.

(2) The percentage basis of the computation, *i.e.*, the actual funds ratio or the optional 20 percent, must be disclosed in the heading of the column.

(C) If the commodity trading advisor elects to include the aggregate of the nominal account sizes of the client accounts in the trading program specified, this information must be placed adjacent to the disclosure of actual funds under management by the commodity trading advisor as required by § 4.35(a)(1)(iv).

(2) Additional requirements with respect to the offered trading program.

* * * * *

(iv) The commodity trading advisor must make available to prospective and existing clients upon request a table showing the information required to be calculated pursuant to § 4.35(a)(6). This table must be updated at least quarterly.

* * * * *

(6) Calculation of, and recordkeeping concerning, performance information.

(i) * * *

(A) The nominal account size at the beginning of the period, defined as the previous period's ending nominal account size;

(B)(1) The net performance for the period, which is defined as the total of:

(i) The realized gain or loss on positions closed during the period, plus

(ii) The change during the period in unrealized gain or loss, plus

(iii) Interest income on funds on deposit in an account at a futures commission merchant to margin the client account which a commodity trading advisor directs, plus

(iv) Other income earned on positions held as part of the CTA's program, minus

(v) Fees and expenses.

(2) No interest or other income may be imputed with respect to nominal account sizes or otherwise computed on a pro-forma basis.

(C) The nominal rate of return for the period, which must be compounded no less frequently than monthly and which shall be calculated by one of the following three methods, consistently applied:

(1) Computing the net performance divided by the beginning nominal account size for each trading day in the period and compounding each daily rate of return to determine the rate of return for the period;

(2) Dividing the net performance by the arithmetic mean of the nominal account sizes for each trading day during the period; or,

(3) Dividing the net performance by the nominal account size at the beginning of the period.

(D) Changes to the nominal account size during the period, pursuant to the terms of the commodity trading advisor's agreement with the client in accordance with § 4.33(c)(4). The records should clearly delineate the source of each change (additions or withdrawals of actual funds, profits or losses, or otherwise).

(E) Changes to the nominal account size pursuant to the terms of the commodity trading advisor's agreement with the client in accordance with § 4.33(c)(1). The records should clearly delineate the source of each change (the opening or closing of accounts during the period or changes to nominal account size specifically directed by a client in writing). If a client and the advisor agree that a nominal account

size be changed effective at the beginning of a period, the change shall be reflected at the end of the prior period.

(F) The nominal account size at the end of the period, defined as the sum of the nominal account size at the beginning of the period [§ 4.35(a)(6)(i)(A)] and the changes specified in this § 4.35(a)(6)(i) subparagraphs (D) and (E).

(ii) All supporting documents necessary to substantiate the computation of such amounts must be maintained in accordance with § 1.31.

* * * * *

Issued in Washington, DC on March 10, 2003 by the Commission.

**Jean A. Webb,**

*Secretary of the Commission.*

[FR Doc. 03–6081 Filed 3–12–03; 8:45 am]

BILLING CODE 6351–01–U

## DEPARTMENT OF THE TREASURY

## Customs Service

## 19 CFR PART 181

**RIN 1515–AD23**

## Tariff Treatment Related to Disassembly Operations Under the North American Free Trade Agreement

**AGENCY:** Customs Service, Department of the Treasury.

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes to amend the Customs Regulations concerning the North American Free Trade Agreement (the NAFTA). Specifically, the proposed rule would allow components which are recovered from the disassembly of used goods in a NAFTA country to be entitled to NAFTA originating status when imported into the United States, provided that: The recovered components satisfy the applicable NAFTA rule of origin requirements; and if the applicable rule of origin does not include a regional value content requirement, the components are subject to further processing in the NAFTA country beyond certain minor operations.

The proposed rule is intended to promote economic activity and the protection of the environment in North America, both of which are goals of the NAFTA. To this end, the recovery and recycling of used goods is a critical element in both the economic activity and the environmental goals of the nation, and disassembly for the recovery of used goods is a key process in many such recycling operations.

**DATES:** Comments must be received on or before May 12, 2003.

**ADDRESSES:** Written comments are to be addressed to the U.S. Customs Service, Office of Regulations and Rulings, Attention: Regulations Branch, 1300 Pennsylvania Avenue, NW., Washington, DC 20229. Submitted comments may be inspected at U.S. Customs Service, 799 9th Street, NW., Washington, DC during regular business hours. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572–8768.

**FOR FURTHER INFORMATION CONTACT:** Edward M. Leigh, Office of Regulations and Rulings, (202) 572–8827.

**SUPPLEMENTARY INFORMATION:**

### Background

On December 17, 1992, the United States, Canada and Mexico (the parties) entered into an agreement, the North American Free Trade Agreement (the NAFTA). The provisions of the NAFTA were adopted by the United States with the enactment of the North American Free Trade Agreement Implementation Act, Public Law 103–182, 107 Stat. 2057 (December 8, 1993).

The question has arisen, in the context of recycling or re-manufacturing operations, whether disassembly occurring in a NAFTA country may be considered NAFTA origin conferring ''production'' where the components recovered by disassembly satisfy the Annex 401 rules of origin for the NAFTA and there is some form of substantial processing performed on the recovered components.

The NAFTA does not explicitly address whether parts or components, whose origin is non-NAFTA or unknown, that are recovered by disassembly in a NAFTA country from a non-originating good, may qualify as NAFTA originating goods if, as a result of the disassembly, they satisfy the rules of origin set out in Article 401 and Annex 401 of the NAFTA and are themselves subjected to some form of substantial further processing.

The recovery and recycling of used goods is an increasingly important element in the economic activity as well as the environmental goals of the nation, and disassembly, for the recovery of parts or for the re-manufacturing of a good, is a key process in many recycling operations.

The goals of the North American Free Trade Agreement (NAFTA) include elimination of barriers to trade, facilitation of cross-border movement of goods, promotion of economic activity in North America, and protection of the environment. The Department of the Treasury and Customs Service have examined NAFTA's rules of origin as applied to both recovered and recycled goods. Allowing disassembly to confer origin under certain circumstances promotes recycling and re-manufacturing in North America and would advance these economic and environmental objectives.

### Proposed Rule

To this end, accordingly, this document proposes to amend the Customs Regulations to allow components which are recovered from the disassembly of used goods in a NAFTA country to be entitled to NAFTA originating status upon importation to the United States, provided that: (1) The recovered components satisfy the applicable NAFTA rule of origin requirements in Annex 401; and (2) if the rule of origin in Annex 401 applicable to the components does not include a regional value content requirement, the components are subject to further processing in the NAFTA country beyond certain specified minor operations.

### Treatment of Disassembly as a Production Consistent with the Intent of NAFTA

Under the proposal, treatment of disassembly as potentially conferring NAFTA originating status must, of course, be consistent with the terms and objectives of the NAFTA Implementation Act of 1993. Within that framework, the most important question which must be answered is does ''disassembly'' constitute origin conferring ''production'' within the meaning of that term as defined in Article 415 of the NAFTA, as implemented in 19 U.S.C. 3332(a)(1)(B)(i) and 3332(p)(22) and in section 2(1) of the NAFTA Rules of Origin Regulations (Uniform Regulations) (19 CFR part 181, Appendix, section 2(1))?

### A Change in Tariff Classification Resulting from a Production

Under NAFTA Article 401(b) and 19 U.S.C. 3332(a)(1)(B)(i), a good shall originate in the territory of a party where each of the non-originating materials used in the production of the good undergoes an applicable change in tariff classification set out in Annex 401 as a result of production occurring entirely in the territory of one or more of the parties. It is therefore understood that unless it results from an activity

that qualifies as ''production'', the mere fact that there is a prescribed change in tariff classification will not be considered as meeting a rule of origin.

The term ''production'' is defined in Article 415 of the NAFTA and in 19 U.S.C. 3332(p)(22) and is implemented in section 2(1) of the Uniform Regulations (19 CFR part 181, Appendix, section 2(1)). As noted, the term, in relevant part, requires a manufacturing, processing or assembling of a good. Of course, the processes listed here are illustrative, not exhaustive, and the absence of the term ''disassembly'' is not dispositive of whether or not a disassembly operation is a production process for NAFTA purposes.

A disassembly operation will result in one or more articles being taken or separated from a manufactured good. Assuming no further production, these various articles are typically classifiable under tariff provisions (often those for ''parts'' of goods) other than the classification of the original good from which the articles were disassembled. Consequently, if disassembly is treated as production and any other requirements are satisfied, the recovered component may satisfy the NAFTA rules of origin.

**Disassembly as a Production Process**

Upon review, we find no evidence (beyond the failure to explicitly include disassembly in the illustrative list of ''production'' activities in NAFTA Article 415) showing that the NAFTA intended not to treat ''disassembly'' as a production process. Use of the term ''processing'' includes a broad range of economic activity within production. Recycling operations for the recovery by disassembly of reusable components such as automotive parts and photocopier or computer parts constitute identifiable business operations within the NAFTA territories and the free trade purposes of NAFTA (discussed above) would be satisfied by establishing rules under which substantial ''production'' consistent with those purposes will be deemed to occur. Recycling operations based on certain repair or alteration operations already have been given appropriate recognition under NAFTA Article 307. Equally, operations based on the recovery of certain waste or scrap materials have been designated in the NAFTA rules of origin as conferring origin where such operations take place (NAFTA Article 415). It is thus consistent with the NAFTA to treat the recovery of useable goods by disassembly as ''production'' under the NAFTA rules of origin.

**Circumvention of NAFTA's Rules of Origin; Disassembly of New Products**

Moreover, to ensure that disassembly is not used to circumvent the intent of NAFTA, the proposed rule provides that, under certain circumstances, additional operations beyond disassembly are required for the recovered component to acquire NAFTA originating status. Specifically, as previously outlined, the recovered component must meet the requirement of the applicable rule of origin in Annex 401, including any pertinent regional value content requirement; and, if the applicable rule of origin in Annex 401 does not include a regional value content requirement, the recovered component must be subject to additional processing beyond certain minor operations.

Where there is no regional value content requirement applicable to the recovered components, the additional processing operations necessary to confer NAFTA originating status must involve more than certain minor operations which are enumerated as follows: (1) Cleaning or sterilizing, including removal of rust, grease, paint, or other coatings; (2) Application of preservative or decorative coatings, including lubricants, protective encapsulation, preservative or decorative paint, or metallic coatings; (3) Trimming, filing or cutting off small amounts of excess materials (precision machining, however, is not to be considered a minor operation); (4) Unloading, reloading or any other operation necessary to maintain the good in good condition; (5) Packing, re-packing, packaging or repackaging; or (6) Testing, marking, sorting, or grading.

Customs has also examined whether a producer might use disassembly of new goods to circumvent the intent of the NAFTA. A new non-NAFTA product could be imported into Mexico or Canada, disassembled, and the disassembled parts could then be imported into the United States and either re-assembled or used as parts. Customs believes that a change in tariff classification resulting from the disassembly of new, non-originating goods should not make the resulting goods eligible for originating status. Because the disassembly of new goods may potentially be treated as a circumvention activity within the meaning of section 17 of the Uniform Regulations (19 CFR part 181, Appendix, section 17), the proposed rule provides that the disassembly of new goods shall not be considered to be ''production'' for the purposes of NAFTA Article 415 and the NAFTA rules of origin. Notwithstanding this proposal, Customs is particularly interested in receiving comments on the contrary view that an applicable value content rule or alternative requirement for substantial processing suffice to permit ''production'' to be considered to have occurred in this case as well. After reviewing the comments, Customs will issue a final rule that will resolve the question definitively.

To reflect the above-described interpretations of law and substantive considerations, this document proposes to add a new § 181.132 to the Customs Regulations (19 CFR 181.132).

**Comments**

Before adopting the proposed regulation, consideration will be given to any written comments that are timely submitted to Customs. Customs specifically requests comments on the clarity of the proposed rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.5, Treasury Department Regulations (31 CFR 1.5) and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), at the U.S. Customs Service, 799 9th Street, NW., Washington, DC during regular business hours. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572–8768.

**Regulatory Flexibility Act and Executive Order 12866**

The proposed rule is intended to promote economic activity as well as the protection of the environment in North America, both of which are goals of the NAFTA. Specifically, the recovery and recycling of used goods is a critical element in both the economic activity and the environmental goals of the nation, and disassembly, for the recovery or re-manufacturing of used goods, is a key process in many such operations. Hence, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604. Nor does the proposed rule result in a ''significant regulatory action'' under E.O. 12866.

**List of Subjects in 19 CFR Part 181**

Administrative practice and procedure, Canada, Customs duties and inspection, Imports, Mexico, Trade

agreements (North American Free-Trade Agreement).

**Proposed Amendments to the Regulations**

It is proposed to amend part 181, Customs Regulations (19 CFR part 181), as set forth below.

## PART 181—NORTH AMERICAN FREE TRADE AGREEMENT

1. The authority citation for part 181 would continue to read as follows:

**Authority:** 19 U.S.C. 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States), 1624, 3314.

2. Subpart L of part 181 is amended by adding a new § 181.132 to read as follows:

**§ 181.132 Disassembly.**

(a) *Treated as a production.* For purposes of implementing the rules of origin provisions of General Note 12, HTSUS, and Chapter Four of the NAFTA, except as provided in paragraph (b) of this section, disassembly is considered to be production, and a component recovered from a good disassembled in the territory of a Party will be considered to be originating as the result of such disassembly provided that:

(1) The recovered component satisfies all applicable requirements of Annex 401 and this part; and

(2) Where the rule in Annex 401 applicable to the recovered component does not include a regional value content requirement, the recovered component is thereafter advanced in value or improved in condition by means of additional processing operations other than those listed below. Merely processing by performing any or all of the following minor operations would not be sufficient to be considered production:

(i) Cleaning or sterilizing, including removal of rust, grease, paint, or other coatings;

(ii) Application of preservative or decorative coatings, including lubricants, protective encapsulation, preservative or decorative paint, or metallic coatings;

(iii) Trimming, filing or cutting off small amounts of excess materials (precision machining, however, is not considered a minor operation);

(iv) Unloading, reloading or any other operation necessary to maintain the good in good condition;

(v) Packing, re-packing, packaging or repackaging; or

(vi) Testing, marking, sorting, or grading.

(b) *Exception; new goods.* Disassembly as provided in paragraph (a) of this section will not be considered a production in the case of components that are recovered from new goods.

(c) *Automotive components/goods.* Notwithstanding the provisions of Schedule V (Automotive Goods) of the Appendix to this part, the rule set forth in this section applies for purposes of determining whether goods of that Schedule are originating.

**Robert C. Bonner,**

*Commissioner of Customs.*

Approved: February 18, 2003.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. 03–6051 Filed 3–12–03; 8:45 am]

BILLING CODE 4820–02–P

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Chapter I

**[OPP–2003–0010; FRL–7298–9]**

**RIN 2070–AD72**

## Endangered Species and Pesticide Regulation; Reopening of Comment Period

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Advance notice of proposed rulemaking; reopening of comment period.

**SUMMARY:** This document reopens the public comment period established in an advance notice of proposed rulemaking (ANPR) issued in the **Federal Register** of January 24, 2003. In that document, EPA sought comment on an ANPR for an endangered species and pesticide regulation. EPA is hereby reopening the comment period, which ended on March 10, 2003. The new comment period will end March 25, 2003.

**DATES:** Comments, identified by the docket ID number OPP–2003–0010, must be received on or before March 25, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION** of the January 24, 2003 **Federal Register** document.

**FOR FURTHER INFORMATION CONTACT:** Arthur-Jean Williams, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5239; fax number: (703) 308–3259; e-mail address: williams.arty@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

This action is directed to the public in general and may be of particular interest to persons who manufacture, sell or use pesticides or who are part of a State or Tribe engaged in the regulation of pesticide products and to groups interested in environmental regulation. The Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult Arthur-Jean Williams at the telephone number/e-mail address listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0010. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR Chapter I is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr1_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public

docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

*C. How and to Whom Do I Submit Comments?*

To submit comments, or access the official public docket, please follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION** of the January 24, 2003 **Federal Register** document. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

## II. Background

On January 24, 2003, EPA, in conjunction with the Fish and Wildlife Service, U.S. Department of the Interior, and National Marine Fisheries Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, issued a **Federal Register** document (68 FR 3785) (FRL–7287–3) seeking public comment on an ANPR for an endangered species and pesticide regulation.

Among the comments received thus far was a request, signed by 30 groups, for an extension of the comment period by 45 days. While the agencies appreciate the need to provide adequate opportunity for public input, the agencies believe a shorter extension is warranted for several reasons. First, numerous comments were already received during the original comment period. Second, the January 24, 2003 **Federal Register** notice was an ANPR. Thus, the public will have further opportunity to comment with future publication of a notice of proposed rulemaking.

## III. What Action is EPA Taking?

Since EPA has an electronic docket system that allows distribution of materials more easily to interested persons, EPA agreed to take responsibility for all of the administrative duties related to publication of the ANPR and this document, including the creation of a public docket, receipt of public comments, and other related matters. Therefore, EPA, on behalf of the three agencies, hereby reopens the comment period, which ended on March 10, 2003. The new comment period will end March 25, 2003.

## IV. What is the Agency's Authority for Taking this Action?

The ANPR was issued under the authority of section 7 of the Endangered Species Act (ESA), as amended, 16 U.S.C. 1531 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

## V. Do Any Statutory and Executive Order Reviews Apply to this Action?

No. This action merely extends the date by which public comments must be submitted to EPA on an ANPR that previously published in the **Federal Register** of January 24, 2003 (68 FR 3785). For information about the applicability of the regulatory assessment requirements to the ANPR, please refer to the discussion in Unit IV. of that document (68 FR 3785).

## List of Subjects

Environmental protection, Endangered species, Pesticides.

Dated: March 10, 2003,

**Stephen L. Johnson,**

*Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.*

[FR Doc. 03–6188 Filed 3–11–03; 2:49 pm]

**BILLING CODE 6560–50–S**

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Parts 51 and 52

**[AD–FRL–7466–9]**

**RIN 2060–AK28**

## Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Routine Maintenance, Repair and Replacement

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Announcement of public hearings and a public comment line.

**SUMMARY:** The EPA is announcing five public hearings to be held on March 31, 2003, on the December 31, 2002, proposal to revise the regulations governing the NSR programs mandated by parts C and D of title I of the Clean Air Act (CAA). The proposed changes provide a future category of activities that would be considered to be routine maintenance, repair and replacement (RMRR) under the NSR program. *See* 67 FR 80290. The public hearings will provide interested parties the opportunity to present data, views, or arguments concerning these proposed changes. The EPA is holding the public hearings because of the number of the requests we received in a timely manner from interested parties throughout the nation. The EPA is also announcing the establishment of a comment line for the public to call and leave verbal comments on these proposed changes. The number is (919) 541–0211. Comments received through this phone number will be logged and placed in Docket No. A–2002–04.

**DATES:** The public hearings will convene at 9 a.m. and will end at 10 p.m. on March 31, 2003. Times are local for each hearing location.

**ADDRESSES:** The public hearings will be held at the following five locations simultaneously:

1. Albany Marriott Hotel, 189 Wolf Road, Albany, NY 12205, Phone 518–458–8444;
2. Doubletree Hotel Dallas, 5410 LBJ Freeway, Dallas, TX 75240, Phone (972) 934–8400;
3. Crowne Plaza Hotel, 8000 Merriman Road, Romulus, MI 48174, Phone 734–729–2600;
4. U.S. Environmental Protection Agency, 109 TW Alexander Drive, Research Triangle Park, North Carolina 27709, Building C, Auditorium C111, phone 919–541–5319; and
5. Hilton Salt Lake City Center, 255 South West Temple, Salt Lake City, UT 84101, Phone 801–328–2000.

Documents related to this proposed rulemaking are available for public inspection in the EPA Air Docket No. A–2002–04.

**FOR FURTHER INFORMATION CONTACT:** Mr. Dave Svendsgaard at (919) 541–2380, telefax (919) 541–5509, E-mail: *svendsgaard.dave@epa.gov* or by mail at U.S. Environmental Protection Agency, OAQPS, Information Transfer and Program Integration Division, (C339–03), Research Triangle Park, North Carolina 27711. As of the date of this announcement, the Agency intends to proceed with the hearings as announced; however, unforeseen circumstances may result in a postponement. Therefore, members of the public planning to attend any of these hearings are advised to contact Ms. Chandra Kennedy, U.S, Environmental Protection Agency, OAQPS, Information Transfer and Program Integration Division, (C339–03), Research Triangle Park, North Carolina 27711; telephone (919) 541–5319 or E-mail *kennedy.chandra@epa.gov*, to confirm the locations and date of the hearings. You may also check our New Source Review website at *http://www.epa.gov/nsr* for any changes in the date or locations. If you would like to speak at any of these hearings, you should also

contact Ms. Chandra Kennedy. Presentations will be limited to 5 minutes each.

**SUPPLEMENTARY INFORMATION:** The EPA's planned seating arrangements for the hearings is theater style, with seating available on a first come first served basis for about 250 people. An agenda will be provided at the hearings.

Dated: March 7, 2003.

**Henry C. Thomas,**

*Acting Director, Office of Air Quality Planning and Standards.*

[FR Doc. 03–6186 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR 62

**[Region II Docket No. NY58–253b; FRL–7464–7]**

## Approval and Promulgation of Implementation Plans for Designated Facilities; NY

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve the State plan submitted by New York State to implement and enforce the Emission Guidelines (EG) for existing small Municipal Waste Combustion (MWC) Units. New York's plan establishes emission limits and other requirements for the purpose of reducing toxic air emissions from small MWC units throughout the State. New York submitted its plan to fulfill the requirements of sections 111(d) and 129 of the Clean Air Act. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is approving the State's SIP submittal, as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule.

If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

**DATES:** Written comments must be received on or before April 14, 2003.

**ADDRESSES:** All comments should be addressed to: Raymond Werner, Chief, Air Programs Branch, Environmental Protection Agency, Region II Office, 290 Broadway, New York, New York 10007–1866.

Copies of the State submittal are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region II Office, 290 Broadway, 25th Floor, New York, New York 10007–1866.

New York State Department of Environmental Conservation, Division of Air Resources, 625 Broadway, 2nd Floor, Albany, New York 12233.

**FOR FURTHER INFORMATION CONTACT:** Anthony (Ted) Gardella, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10278, (212) 637–4249.

**SUPPLEMENTARY INFORMATION:** For additional information see the direct final rule which is located in the Rules Section of this **Federal Register**.

Dated: March 3, 2003.

**Jane M. Kenny,**

*Regional Administrator, Region 2.*

[FR Doc. 03–5909 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 271

**[FRL–7465–9]**

## Virginia: Final Authorization of State Hazardous Waste Management Program Revision

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Virginia has applied to EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant final authorization to Virginia. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble to the immediate final rule. Unless we receive written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we receive comments that oppose this action, we will withdraw the immediate final rule, and it will not take effect. We will then respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment. If you want to comment on this action, you must do so at this time.

**DATES:** Send your written comments by April 14, 2003.

**ADDRESSES:** Send written comments to Joanne Cassidy, Mailcode 3WC21, RCRA State Programs Branch, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–3381. You may inspect and copy Virginia's application from 8:15 a.m. to 4:30 p.m. at the following locations: Virginia Department of Environmental Quality, 629 East Main Street, Richmond, VA 23219, Phone Number: (804) 698–4213, attn: Robert Wickline; or Virginia Department of Environmental Quality, West Central Regional Office, 3019 Peters Creek Road, Roanoke, VA 24015, Phone Number: (540) 562–6872, attn: Aziz Farahmand; or EPA Region III, Library, 2nd Floor, 1650 Arch Street, Philadelphia, PA 19103–2029, Phone Number: (215) 814–5254.

**FOR FURTHER INFORMATION CONTACT:** Joanne Cassidy, Mailcode 3WC21, RCRA State Programs Branch, U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA 19103, Phone number: (215) 814–3381.

**SUPPLEMENTARY INFORMATION:** For additional information, please see the immediate final rule published in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: March 5, 2003.

**Thomas Voltaggio,**

*Acting Regional Administrator, Region III.*

[FR Doc. 03–6110 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 15

**[ET Docket No. 00–258 and IB Docket No. 99–81; FCC 03–16]**

## Advanced Wireless Service

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document seeks comment on how to use the reallocated Mobile Satellite Service (MSS) spectrum

as well as other bands previously proposed for Advanced Wireless Service (AWS) use, the relocation of the Multipoint Distribution Service (MDS), and additional flexibility for the Unlicensed Personal Communications Service (UPCS) band spectrum, in order to promote more efficient spectrum use which, in turn, serves the public interest.

**DATES:** Written comments are due April 14, 2003, and reply comments are due April 28, 2003.

**ADDRESSES:** Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., TW–A325, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Jamison Prime, Office of Engineering and Technology, (202) 418–7474, TTY (202) 418–2989, e-mail: *jprime@fcc.gov.*

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Third Notice of Proposed Rule Making,* ET Docket 00–258 and IB Docket No. 99–81, FCC 03–16, adopted January 29, 2003, and released February 10, 2003. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 or TTY (202) 418–7365.

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments on or before April 14, 2003, and reply comments on or before April 28, 2003. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121, May 1, 1998. Comments filed through the ECFS can be sent as an electronic file via the Internet to *http://www.fcc.gov/e-file/ecfs.html.* Generally, only one copy of an electronic submission must be filed. If multiple docket or rulemaking numbers appear in the caption of this proceeding, however, commenters must transmit one electronic copy of the comments to each docket or rulemaking number referenced in the caption. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message, ''get form <your e-mail address.'' A sample form and directions will be sent in reply. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appear in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number.

All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). The Commission's contractor, Vistronix, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743. U.S. Postal Service first-class mail, Express Mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

## Summary of Third Notice of Proposed Rule Making

1. The *Third Notice of Proposed Rule Making* (''Third NPRM'') discusses the frequency bands that are still under consideration in this proceeding and invites additional comment on their disposition. Specifically, we address the UPCS band at 1910–1930 MHz, the MDS spectrum at 2155–2160/62 MHz, the Emerging Technology spectrum at 2160–2165 MHz, and the bands reallocated from MSS (1990–2000 MHz, 2020–2025 MHz and 2165–2180 MHz). We seek comment on these bands with respect to using them for paired or unpaired AWS operations or as relocation spectrum for existing services. We emphasize the scope of the record we have already developed and urge interested parties to narrow their discussion to specific proposals that will allow for the most efficient and effective use of this remaining spectrum. For example, parties filing comments in response to any of the issues in the *Third Notice* should take into account how the modification of our rules to allow MSS licensees to deploy ATC (*see* Flexibility for Delivery of Commmunications by Mobile Satellite Service Providers in the 2 GHz Band, the L-Band and the 1.6/2.4 GHz Bands, FCC 03–315) affects their analysis of the spectrum under consideration in this proceeding. We specifically seek comment on the following issues:

- Seek comment on whether we should re-designate all or a portion of the UPCS spectrum at 1910–1920 for new fixed and mobile uses. Five or 10 megahertz of this spectrum could be paired with spectrum in the 1990–2000 MHz band to expand the existing Broadband PCS allocation, to allow for AWS applications, or as replacement spectrum for other services.
- Tentatively conclude that we should retain the 1920–1930 MHz band for UPCS use and seek comment on whether we should provide for additional flexibility in that band, as well as any additional spectrum that we retain for UPCS use in the 1910–1920 MHz band.
- Seek comment on making available for new services, including AWS, the MSS uplink band spectrum that we are reallocating at 2020–2025 MHz. We also ask whether this band could be paired with spectrum in the 2.1 GHz band.
- Seek further comment on making available for new services, including AWS, a 10 megahertz block that is upper adjacent to the existing 45 megahertz AWS allocation in the 2110–2155 MHz band. This spectrum block consists of the remaining 5 megahertz of the MDS band at 2155–2160 MHz combined with an adjacent 5 megahertz spectrum block in the 2160–2165 MHz band that was identified in the *Emerging Technologies* proceeding.
- Seek comment on the best use of the spectrum that we make available by reallocating the MSS downlink band at 2165–2180 MHz.
- Seek comment on relocation spectrum for MDS operations from the 2150–2160/62 MHz band, including spectrum that we make available by reallocating the MSS downlink band at 2165–2180 MHz or, alternatively, spectrum that is adjacent to the Broadband PCS bands.

## Initial Regulatory Flexibility Analysis

2. As required by the Regulatory Flexibility Act (RFA) [1] the Commission

[1] See 5 U.S.C. 603. The RFA (codified at 5 U.S.C. 601–612) has been amended by the Small Business

has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this Third Notice of Proposed Rulemaking (*Third NPRM*). Comment is requested in this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the *Third NPRM* as provided in paragraph 77 of the *Third NPRM*. The Commission will send a copy of the *Third NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. See 5 U.S.C. 603(a).

*Need for, and Objectives of, the Proposed Rules*

3. The *Third NPRM* seeks comments on the reallocation of spectrum in the 1910–1920 MHz band that can be paired with spectrum in the 1990–2000 MHz band to support fixed and mobile services, including AWS. It proposes that additional flexibility be afforded to the UPCS spectrum (that remains in the 1910–1930 MHz band) in order to support a variety of UPCS devices, including voice and data devices, and asks whether additional unlicensed devices—such as community wireless networks—could also coexist in the band. The *Third NPRM* also proposes to reallocate spectrum at 2155–2165 MHz that was previously identified as candidate spectrum for AWS, and seeks the most appropriate means to relocate licensees operating in the 2150–2160/2162 MHz band. Together, these proposed actions continue our efforts to identify spectrum that is suitable for AWS, and to allocate our existing in such a way as to promote overall efficient use.

*Legal Basis*

4. The proposed action is authorized under sections 1, 4(i), 7(a), 301, 302(a), 303(f), 303(g), 303(r), 307, 308, 309(j), 316, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. sections 151, 154(i), 157(a), 301, 302(a), 303(f), 303(g), 303(r), 307, 308, 309(j), 316, and 332.

*Description and Estimate of the Number of Small Entities to Which the Rules Will Apply*

5. The RFA directs agencies to provide a description of, and, where feasible, an estimate of, the number of small entities that may be affected by the rules adopted herein.[2] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[3] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[4] A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).[5]

6. A small organization is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.''[6] Nationwide, as of 1992, there were approximately 275,801 small organizations.[7] ''Small governmental jurisdiction'' generally means ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.''[8] As of 1992, there were approximately 85,006 governmental entities in the United States.[9] This number includes 38,978 counties, cities, and towns; of these, 37,566, or 96%, have populations of fewer then 50,000.[10] The Census Bureau estimates that this ratio is approximately accurate for all governmental entities. Thus, of the 85,006 governmental entities, we estimate that 81,600 (96%) are small entities.

*Radiotelephone Operators.* The Commission has not developed service rules for AWS spectrum, nor has it attempted to categorize potential licensees for this spectrum. However, because many of the comments we received in support of our efforts to allocate spectrum for AWS were submitted by commercial radiotelephone operators and because licensees of AWS-like bands in other countries include incumbent commercial radiotelephone operators, we believe that there is a high likelihood that the class of AWS licensees may ultimately consist of one or more radiotelephone operator. Therefore, we examine this category in greater depth. The SBA has developed a small business size standard for small businesses in the category ''Cellular and Other Wireless Telecommunications.''[11] Under that SBA category, a business is small if it has 1,500 or fewer employees.[12] According to the Bureau of the Census, only 12 firms from a total of 1238 cellular and other wireless telecommunications firms operating during 1997 had 1,000 or more employees.[13] Therefore, even if all 12 of these firms were cellular telephone companies, nearly all cellular carriers were small businesses under the SBA's definition. In addition, we note that there are 1807 cellular licenses; however, a cellular licensee may own several licenses. According to the most recent *Trends in Telephone Service* data, 858 carriers reported that they were engaged in the provision of either cellular service, Personal Communications Service (PCS), or Specialized Mobile Radio telephony services, which are placed together in that data. We have estimated that 291 of these are small under the SBA small business size standard.[14] Accordingly, based on this data, we estimate that not more than 291 radiotelephone operators would be affected by a decision to make additional spectrum available for AWS.

*Fixed Microwave Services.* The *Third NPRM* proposes to reallocate a 5 megahertz spectrum block (2160–2165 MHz) that is licensed to fixed point-to-point microwave services and was previously identified for reallocation for advanced services in the Commission's *Emerging Technologies* proceeding.[15]

Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, title II, 110 Stat. 857 (1996).

[2] 5 U.S.C. 604(a)(3).

[3] 5 U.S.C. 601(6).

[4] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small-business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[5] 15 U.S.C. 632.

[6] 5 U.S.C. 601(4).

[7] Department of Commerce, U.S. Bureau of the Census, 1992 Economic Census, Table 6 (special tabulation of data under contract to Office of Advocacy of the U.S. Small Business Administration).

[8] 5 U.S.C. 601(5).

[9] U.S. Dept. of Commerce, Bureau of the Census, ''1992 Census of Governments.''

[10] Id.

[11] 13 CFR 121.201, North American Industry Classification System (NAICS) code 513322.

[12] Id.

[13] U.S. Department of Commerce, U.S. Census Bureau, 1997 Economic Census, Information—Subject Series, Establishment and Firm Size, Table 5—Employment Size of Firms Subject to Federal Income Tax at 64, NAICS code 513322 (October 2000).

[14] See Trends in Telephone Service, Industry Analysis and Technology Division, Wireline Communications Bureau, Table 5.3, page 5–5 (May 2002).

[15] Redevelopment of Spectrum to Encourage the Establishment of Services Using New and Innovative Technologies, ET Docket No. 92–9, First Report and Order and Third Notice of Proposed Rule Making, 7 FCC Rcd 6886 (1992), 57 FR 49020, October 10, 1992 and 57 FR 48776, October 28, 1992; Second Report and Order, 8 FCC Rcd 6495 (1993), 58 FR 49220, September 22, 1993; Third Report and Order and Memorandum Opinion and

Continued

Microwave services include common carrier,[16] private-operational fixed,[17] and broadcast auxiliary radio services.[18] At present, there are approximately 22,015 common carrier fixed licensees and 61,670 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services. The Commission has not yet defined a small business with respect to microwave services. For purposes of this FRFA, we will use the SBA's definition applicable to wireless and other telecommunications companies—*i.e.*, an entity with no more than 1,500 persons.[19] According to Census Bureau data for 1997, there were 977 firms in this category, total, that operated for the entire year.[20] Of this total, 965 firms had employment of 999 or fewer employees, and an additional 12 firms had employment of 1,000 employees or more.[21] Thus, under this size standard, the great majority of firms can be considered small.

7. We note that the number of firms does not necessarily track the number of licensees. We estimate that all of the Fixed Microwave licensees (excluding broadcast auxiliary licensees) would qualify as small entities under the SBA definition. Of these licenses, approximately 890 are issued for frequencies in the Emerging Technology bands affected by this proceeding. In addition, the band contains approximately 13 licenses in the paging and radiotelephone service and 40 Local Television Transmission Service licenses. Thus, assuming that these entities also qualify as small businesses, as many as 943 small business licensees could be affected by the rules we adopt. We note that these entities have been subject to relocation under rules originally adopted in the Commission's *Emerging Technologies* proceeding. The *Third NPRM* anticipates that these general relocation rules will continue to apply to FS microwave licensees and does not propose to modify the class of licensees that are subject to these relocation provisions.

*Multipoint Distribution Service (MDS).* The *Third NPRM* proposes to reallocate spectrum for MDS licensees that currently operate in the 2155–2160 MHz band (and the 2155–2162 MHz band in some cases). This service has historically provided primarily point-to-multipoint, one-way video services to subscribers.[22] The Commission recently amended its rules to allow MDS licensees in the 2500–2690 MHz band to provide a wide range of high-speed, two-way services to a variety of users.[23] In connection with the 1996 MDS auction, the Commission defined small businesses as entities that had annual average gross revenues for the three preceding years not in excess of $40 million.[24] The Commission established this small business definition in the context of this particular service and with the approval of the SBA.[25] The MDS auction resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas (BTAs).[26] Of the 67 auction winners, 61 met the definition of a small business. At this time, we estimate that of the 61 small business MDS auction winners, 48 remain small business licensees. In addition to the 48 small businesses that hold BTA authorizations, there are approximately 392 incumbent MDS licensees that are considered small entities.[27] After adding the number of small business auction licensees to the number of incumbent licensees not already counted, we find that there are currently approximately 440 MDS licensees that are defined as small businesses under either the SBA or the Commission's rules. Because the Commission's action only affects MDS operations in the 2155–2160 MHz band (and 2155–2162 MHz band in some cases), the actual number of MDS providers who will be affected by the proposed reallocation will only represent a small fraction of those 440 small business licensees.

*Unlicensed Personal Communications Service (UPCS).* As its name indicates, UPCS is not a licensed service. UPCS consists of intentional radiators operating in the frequency bands 1910–1930 MHz and 2390–2400 MHz, that provide a wide array of mobile and ancillary fixed communication services to individuals and businesses. The Third NPRM affects UPCS operations in the 1910–1920 MHz band; operations in those frequencies are limited to asynchronous (generally data) applications. There is no accurate source for the number of operators in the UPCS. The Commission has not developed a definition of small entities applicable to UPCS equipment manufacturers. However, the SBA has developed a small business size standard, Cellular and Other Wireless Carriers, which consists of all such companies having 1500 or fewer employees.[28] According to Census Bureau data for 1997, there were 977 firms in this category, total, that operated for the entire year.[29] Of this total, 965 firms had employment of 999 or fewer employees, and an additional 12 firms had employment of 1,000 employees or more.[30] Thus, under this

Order, 8 FCC Rcd 6589 (1993), 58 FR 46547, October 4, 1993; Memorandum Opinion and Order, 9 FCC Rcd 1943 (1994), 59 FR 19642, April 25, 1994; Second Memorandum Opinion and Order, 9 FCC Rcd 7797 (1994), 59 FR 65501, December 20, 1994, aff'd, Association of Public Safety Communications Officials-International, Inc. v. FCC, 76 F.3d 395 (D.C. Cir. 1996) (collectively, ''Emerging Technologies proceeding'').

[16] 47 CFR 101 *et seq.* (formerly, part 21 of the Commission's Rules).

[17] Persons eligible under parts 80 and 90 of the Commission's rules can use Private Operational-Fixed Microwave services. See 47 CFR parts 80 and 90. Stations in this service are called operational-fixed to distinguish them from common carrier and public fixed stations. Only the licensee may use the operational-fixed station, and only for communications related to the licensee's commercial, industrial, or safety operations.

[18] Auxiliary Microwave Service is governed by part 74 of title 47 of the Commission's rules. See 47 CFR part 74 *et seq.* Available to licensees of broadcast stations and to broadcast and cable network entities, broadcast auxiliary microwave stations are used for relaying broadcast television signals from the studio to the transmitter, or between two points such as a main studio and an auxiliary studio. The service also includes mobile TV pickups, which relay signals from a remote location back to the studio.

[19] 13 CFR 121.201, NAICS code 517212 (formerly 513322).

[20] U.S. Census Bureau, 1997 Economic Census, Subject Series: Information, ''Employment Size of Firms Subject to Federal Income Tax: 1997,'' Table 5, NAICS code 517212 (issued Oct. 2000).

[21] Id. The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is ''Firms with 1,000 employees or more.''

[22] For purposes of this item, MDS includes single channel Multipoint Distribution Service (MDS) and the Multichannel Multipoint Distribution Service (MMDS). See 66 FR 36177.

[23] Amendment of parts 21 and 74 to Enable Multipoint Distribution Service and Instructional Television Fixed Service Licensees to Engage in Fixed Two-Way Transmissions, MM Docket No. 97–217, Report and Order, 13 FCC Rcd 19112 (1998), 63 FR 65087, November 25, 1998, recon., 14 FCC Rcd 12764 (1999), 64 FR 63727, November 22, 1999, further recon., 15 FCC Rcd 14566 (2000).

[24] 47 CFR 21.961 and 1.2110.

[25] Amendment of parts 21 and 74 of the Commission's Rules with Regard to Filing Procedures in the Multipoint Distribution Service and in the Instructional Television Fixed Service and Implementation of section 309(j) of the Communications Act—Competitive Bidding, MM Docket No. 94–131, Report and Order, 10 FCC Rcd 9589, 9670 (1995), 60 FR 36524 (July 17, 1995).

[26] Basic Trading Areas (BTAs) were designed by Rand McNally and are the geographic areas by which MDS was auctioned and authorized. See id. at 9608.

[27] 47 U.S.C. 309(j). (Hundreds of stations were licensed to incumbent MDS licensees prior to implementation of Section 309(j) of the Communications Act of 1934, 47 U.S.C. 309(j)). For these pre-auction licenses, the applicable standard is SBA's small business size standard for ''other telecommunications'' (annual receipts of $12.5 million or less). See 13 CFR 121.201.

[28] 13 CFR 121.201, North American Industry Classification System (NAICS) code 517212.

[29] U.S. Census Bureau, 1997 Economic Census, Subject Series: Information, ''Employment Size of Firms Subject to Federal Income Tax: 1997,'' Table 5, NAICS code 517212 (issued Oct. 2000).

[30] Id. The census data do not provide a more precise estimate of the number of firms that have

size standard, the great majority of firms can be considered small. However, no equipment authorizations have been issued for devices operating in the 1910–1920 MHz band.

*Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements*

9. The *Third NPRM* addresses the possible use of frequency bands below 3 GHz to support the introduction of new AWS, but does not propose service rules. Thus, the item contains no new reporting, recordkeeping, or other compliance requirements.

*Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered*

10. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): ''(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.'' [31]

11. Providing spectrum to support the introduction of new advanced mobile and fixed terrestrial wireless services is critical to the continuation of technological advancement. As an initial matter, we believe that the provision of additional spectrum that can be used to support AWS will directly benefit small business entities by providing new opportunities for the provision of innovative new fixed and mobile wireless services.

12. We realize that some entities must be displaced to clear a sufficient quantity of contiguous spectrum to support new services. We endeavored to avoid this effect by identifying unencumbered spectrum, but spectrum in the suitable frequency range is heavily used already and a sufficient amount of unencumbered spectrum simply does not exist. We have also sought to minimize an adverse impact by proposing to reallocate frequency bands for those incumbents, including small entities, which might be accommodated in other spectrum. The spectrum we propose to allocate in the 2160–2165 MHz band was previously identified as an Emerging Technology band; thus, we have previously considered relocation consequences and established relocation procedures for incumbent operators in this band. Small entities operating in this band have known for a decade that they are subject to relocation and may have taken steps (such as deploying more efficient systems in different spectrum in lieu of upgrading existing equipment) that could minimize the consequences of relocation vis-à-vis licensees in another spectrum band that had not heretofore been identified as a candidate for reallocation. Thus, the existing relocation procedures should serve to ease the relocation of small entity incumbents in the 2160–2165 MHz band, and make reallocation of this band a preferable alternative to the reallocation of other bands where we would have to establish new relocation rules.

13. The Commission has already received extensive comments in this proceeding on issues related to the possible reallocation of the 2150–2160 MHz (2.1 GHz) spectrum for advanced wireless purposes. Comments filed by the multipoint distribution/instructional television fixed services industry and several equipment manufacturers argue that the 2.1 GHz band is necessary for the continued roll-out of fixed wireless services across the country. Other commenters support the use of 2.1 GHz for advanced wireless services. In a recent decision, the Commission determined that it was necessary to reallocate MDS operations at 2150–2155 MHz to create a 45 megahertz block of contiguous spectrum that can be used to provide advanced services, but did not decide how to relocate these operations or what to do with remaining MDS operations in the 2155–2160/62 MHz band. One option proposed is the reallocation of the remaining MDS spectrum. By taking this action, we would be able to provide opportunities associated with the provision of contiguous and/or paired blocks of spectrum that can be used for fixed and mobile applications, including AWS.

14. The *Third NPRM* discusses reallocation of UPCS spectrum in the 1910–1920 MHz band for AWS. Because no equipment is currently certified for this band, we conclude that our decision is unlikely to affect any users or equipment manufacturers that are small entities. We also explore options for providing increased flexibility of unlicensed use in the remaining UPCS spectrum, including modifying our rules to allow for expanded voice-based applications in the 1915–1920 MHz portion of the band if we decide to reallocate only the 1910–1915 MHz band segment. We note that we had sought comment on use of the entire 1910–1930 MHz band for AWS, and that the record reflects that numerous small entities may use or manufacture UPCS voice equipment on the 1920–1930 MHz portion of the band. Thus, the *Third R&O* represents a means to provide additional opportunities both to small entities that provide AWS while providing minimal disruption to small entities that are UPCS users and manufacturers (and possibly providing additional benefits, if the proposal to expand permitted UPCS use of the 1915–1920 MHz band is adopted). For this reason we conclude that our action is preferable to other alternatives, such as retaining the existing UPCS allocation in its entirety.

*Rules That May Duplicate, Overlap or Conflict With the Proposed Rules*

15. None.

**List of Subjects in 47 CFR Part 15**

Communications equipment.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

**Proposed Rules**

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 15 as follows:

## PART 15—RADIO FREQUENCY DEVICES

1. The authority citation for part 15 continues to read as follows:

**Authority:** 47 U.S.C. 154, 302, 303, 304, 307, 336, and 544A.

2. Section 15.319 is amended by revising the first sentence in paragraph (a) to read as follows:

**§ 15.319 General technical requirements.**

(a) The 2390–2400 MHz band is limited to use by asynchronous devices under the requirements of § 15.321.

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3. Section 15.321 is amended by revising the section heading and paragraphs (a) and (b) to read as follows:

**§ 15.321 Specific requirements for asynchronous devices operating in the 2390–2400 MHz band.**

(a) Operation shall be contained within the 2390–2400 MHz band. The emission bandwidth of any intentional radiator operating in these bands shall be no less than 500 kHz.

employment of 1,500 or fewer employees; the largest category provided is ''Firms with 1,000 employees or more.''

[31] 5 U.S.C. 603(c)(1)–(c)(4).

(b) All systems of less than 2.5 MHz emission bandwidth shall start searching for an available spectrum window within 3 MHz of the band edge at 2390 or 2400 MHz while systems of more than 2.5 MHz emission bandwidth will first occupy the center half of the band. Devices with an emission bandwidth of less than 1.0 MHz may not occupy the center half of the sub-band if other spectrum is available.

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[FR Doc. 03–6038 Filed 3–12–03; 8:45 am]

BILLING CODE 6712–01–P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 54

**[CC Docket No. 96–45; FCC 03–13]**

## Federal-State Joint Board on Universal Service

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of proposed rule.

**SUMMARY:** In this document, the Commission seeks comment on the *Recommended Decision* of the Federal-State Joint Board on Universal Service (Joint Board) regarding the definition of services supported by universal service. In its *Recommended Decision,* the Joint Board generally recommended that the Commission not modify the existing list of services supported by universal service. The Joint Board was unable to reach agreement, however, on whether equal access to interexchange service (equal access) satisfies the statutory criteria contained in the Communications Act of 1934, as amended, and should be added to the list of supported services. The Commission seeks comment regarding the Joint Board's recommendations and positions.

**DATES:** Comments are due on or before April 14, 2003. Reply comments are due on or before April 28, 2003.

**ADDRESSES:** Federal Communications Commission, 445 12th Street, SW., Suite TW–A325, Marlene H. Dortch, Office of the Secretary, Washington, DC, 20554. *See* **SUPPLEMENTARY INFORMATION** for further filing instructions.

**FOR FURTHER INFORMATION CONTACT:** Katherine Tofigh, Attorney or Diane Law Hsu, Deputy Division Chief, Wireline Competition Bureau, Telecommunications Access Policy Division, (202) 418–7400.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Notice of Proposed Rulemaking in CC Docket No. 96–45 released on February 25, 2003. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 Twelfth Street, SW., Washington, DC 20554.

### I. Notice of Proposed Rulemaking

1. In this Notice of Proposed Rulemaking (NPRM), we seek comment on the *Recommended Decision* of the Federal-State Joint Board on Universal Service (Joint Board) regarding the definition of services supported by universal service. A copy of the *Recommended Decision* can be found at 17 FCC Rcd 14095 (Wir. Com. Bur. rel. Jul. 10, 2002). In its *Recommended Decision,* the Joint Board generally recommended that the Commission not modify the existing list of services supported by universal service. The Joint Board was unable to reach agreement, however, on whether equal access to interexchange service (equal access) satisfies the statutory criteria contained in section 254(c) of the Communications Act of 1934, as amended (the Act), and should be added to the list of supported services. We seek comment regarding the Joint Board's recommendations and positions.

### II. Procedural Issues

*A. Ex Parte Presentations*

2. This is a permit but disclose rulemaking proceeding. Ex parte presentations are permitted, except during the Sunshine Agenda period, as long as they are disclosed as provided in the Commission's rules.

*B. Initial Paperwork Reduction Act Analysis*

3. This NPRM may modify an information collection. As part of a continuing effort to reduce paperwork burdens, we invite the general public and the Office of Management and Budget (OMB) to take this opportunity to comment on the information collections contained in this NPRM, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due at the same time as other comments on this NPRM; OMB comments are due May 12, 2003. Comments should address: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (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 the respondents, including the use of automated collection techniques or other forms of information technology.

*C. Initial Regulatory Flexibility Analysis*

4. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this NPRM. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the NPRM provided. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.

*D. Need for and Objectives of the Proposed Rules*

5. Pursuant to section 254(c) of the Act, the Joint Board on Universal Service may periodically make recommendations to modify the list of supported services, in order to take account for advances in telecommunications and information technologies and services. On December 21, 2000, the Commission requested the Joint Board to review the definition of universal service and make recommendations regarding whether modifications to the definition are warranted. The Joint Board subsequently released a public notice seeking comment on the services, if any, that should be added to or removed from the list of core services. On July 10, 2002, the Joint Board released its recommendations regarding the list of services supported by universal service. The NPRM seeks comment on the Joint Board's recommendations.

1. Legal Basis

6. The legal basis as proposed for this NPRM is contained in §§ 4(i), 4(j), 201–205, 214, 254, and 403 of the Communications Act of 1934, as amended.

2. Description and Estimate of the Number of Small Entities to Which the Proposed Rules will Apply

7. The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposed modifications to the definition of universal services. To

estimate the number of small entities that could be affected by these proposed modifications to the Commission's rules, we first consider the statutory definition of ''small entity'' under the RFA. The RFA defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small business concern'' under the Small Business Act. A small business concern is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

8. We have included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.*, a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

9. The most reliable source of information regarding the total numbers of common carrier and related providers nationwide, including the numbers of commercial wireless entities, appears to be data the Commission publishes annually in its *Trends in Telephone Service* report. These carriers include, *inter alia,* incumbent local exchange carriers, competitive local exchange carriers, competitive access providers, interexchange carriers, other wireline carriers and service providers (including shared-tenant service providers and private carriers), operator service providers, pay telephone operators, providers of telephone toll service, wireless carriers and services providers, and resellers.

10. *Total Number of Telephone Companies Affected.* The United States Bureau of the Census (the ''Census Bureau'') reports that, at the end of 1997, there were 6,239 firms engaged in providing telephone services, as defined therein. This number contains a variety of different categories of carriers, including local exchange carriers, interexchange carriers, competitive access providers, cellular carriers, mobile service carriers, operator service providers, pay telephone operators, PCS providers, covered SMR providers, and resellers. It seems certain that some of those 6,239 telephone service firms may not qualify as small entities because they are not ''independently owned and operated.'' For example, a PCS provider that is affiliated with an interexchange carrier having more than 1,500 employees would not meet the definition of a small business. It is reasonable to conclude, therefore, that 6,239 or fewer telephone service firms are small entity telephone service firms that may be affected by the decisions proposed in this NPRM.

11. *Local Exchange Carriers and Competitive Access Providers.* Neither the Commission nor the SBA has developed a definition for small providers of local exchange services. The closest applicable definition under the SBA rules is for wired telecommunications carriers. This provides that a wired telecommunications carrier is a small entity if it employs no more than 1,500 employees. According to the most recent Commission data there are 1,619 local services providers with 1,500 or fewer employees. Because it seems certain that some of these carriers are not independently owned and operated, we are unable at this time to estimate with greater precision the number of these carriers that would qualify as small business concerns under SBA's definition. Of the 1,619 local service providers, 1,024 are incumbent local exchange carriers, 411 are Competitive Access Providers (CAPs) and Competitive Local Exchange Carriers (CLECs), 131 are resellers and 53 are other local exchange carriers. Consequently, we estimate that fewer than 1,619 providers of local exchange service are small entities or small incumbent local exchange carriers that may be affected.

12. *Interexchange Carriers.* Neither the Commission nor the SBA has developed a definition of small entities specifically applicable to providers of interexchange services (IXCs). The closest applicable definition under the SBA rules is for wired telecommunications carriers. This provides that a wired telecommunications carrier is a small entity if it employs no more than 1,500 employees. According to the most recent Commission data regarding the number of these carriers nationwide of which we are aware appears, there are 181 IXCs with 1,500 or fewer employees. Because it seems certain that some of these carriers are not independently owned and operated, we are unable at this time to estimate with greater precision the number of these carriers that would qualify as small business concerns under SBA's definition. Consequently, we estimate that there are fewer than 181 small entity IXCs that may be affected by the proposals in the NPRM.

13. *Operator Service Providers, Prepaid Calling Card Providers, Satellite Service Carriers, Toll Resellers, Other Toll Carriers, and Payphone Providers.* Neither the Commission nor SBA has developed a definition particular to operator service providers (OSPs), prepaid calling card providers, satellite service carriers, toll resellers, other toll carriers, or payphone providers. The closest applicable definition for these carrier-types under SBA rules is for telephone communications companies other than radiotelephone (wireless) companies. The most reliable source of information regarding the number of these carriers nationwide of which we are aware appears to be the data that we collect annually on the Form 499–A. According to our most recent data, there are 20 OSPs, 31 prepaid calling card providers, 25 satellite service carriers, 538 toll resellers, 37 other toll carriers, and 933 payphone providers that have 1,500 of fewer employees. Although it seems certain that some of these carriers are not independently owned and operated, we are unable at this time to estimate with greater precision the number of these carriers that would qualify as small business concerns under SBA's definition. Consequently, we estimate that there are fewer than 20 OSPs, 31 prepaid calling card providers, 25 satellite service carriers, 538 toll resellers, 37 other toll carriers, and 933 payphone providers may be affected by the decisions and rules adopted in this NPRM.

14. *Cellular and Wireless Telephony.* Neither the Commission nor the SBA has developed a definition of small entities specifically for wireless telephony. The closest definition is the SBA definition for cellular and other wireless telecommunications. Under this definition, a cellular licensee is a small entity if it employs no more than 1,500 employees. According to the most recent Commission data, 858 providers classified themselves as providers of wireless telephony, including cellular telecommunications, Personal Communications Service, and Specialized Mobile Radio (SMR) Telephony Carriers. 291 providers report having 1,500 or fewer employees. We do not have data specifying the number of these carriers that are not independently owned and operated, and thus are unable at this time to estimate with greater precision the number of cellular service carriers that would qualify as small business concerns

under the SBA's definition. Consequently, we estimate that there are fewer than 291 wireless telephony carriers that may be affected.

15. *Other Wireless Services.* Neither the Commission nor the SBA has developed a definition of small entities specifically applicable to wireless services other than wireless telephony. The closest applicable definition under the SBA rules is again that of cellular and other wireless telecommunications, under which a service provider is a small entity if it employs no more than 1,500 employees. According to the most recent Commission data, 884 providers with 1,500 of fewer employees classified themselves as paging services, SMR dispatch, wireless data carriers, or other mobile service providers. We do not have data specifying the number of these carriers that are not independently owned and operated, and thus are unable at this time to estimate with greater precision the number of wireless service providers that would qualify as small business concerns under the SBA's definition. Consequently, we estimate that there are fewer than 884 wireless service providers that may be affected.

3. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

16. Should the Commission decide to revise the definition of universal service, the associated rule changes could modify the reporting and recordkeeping requirements of some telecommunications service providers regulated under the Communications Act.

17. Section 254(e) states that only eligible telecommunications carriers (ETCs) designated pursuant to section 214(e) shall be eligible to receive Federal universal service support. In order to be designated an ETC, a carrier must throughout its service area ''offer the services that are supported by Federal universal service support mechanisms under section 254(c).'' Carriers generally apply to their state commission for designation as carriers eligible to receive universal service support, but seek designation from the Commission if they are not subject to the jurisdiction of the state commission. If the definition of supported services is modified, service provides may be required to verify to either the state or Commission that any services added to the definition of universal service are offered throughout their service areas and that they advertise the availability of such services. Entities, especially small businesses, are encouraged to quantify the cost of compliance for reporting possible additions to the list of supported services.

18. In addition, ETCs may only use support ''for the provision, maintenance, and upgrading of facilities and services'' for supported services. Pursuant to this rule, state regulatory commissions provide the Commission with annual certifications indicating that ETCs in their states receiving federal universal service support will use the support only for its intended purposes. Carriers not subject to the jurisdiction of the state must submit a sworn affidavit to the Commission stating that they will use the support only for its intended purposes. Entities, especially small businesses, are encouraged to quantify the cost of compliance for certifying possible additions to the list of supported services.

4. Steps Taken to Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

19. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

20. As discussed previously, this NPRM seeks comment on the Joint Board's recommendations regarding the definition of universal service. The Joint Board determined that the current list of core services continue to satisfy the criteria outlined in section 254(c) and recommended that the Commission retain the existing services. For most of the additional services under consideration, the Joint Board recommended that the Commission not expand the existing definition of services that are supported by federal universal service. The Joint Board, however, was unable to reach agreement on whether equal access satisfies the statutory criteria contained in section 254(c) of the Act.

21. Should the definition of universal service be modified, we seek comment on how to reduce the administrative burden and cost of compliance for small telecommunications service providers with respect to each of the proposals. We particularly seek comment from carriers that are ''small business concerns'' under the Small Business Act.

5. Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rules

22. None.

*E. Comment Filing Procedures*

23. We invite comment on the issues and questions set forth in the Notice of Proposed Rulemaking and Initial Regulatory Flexibility Analysis contained herein. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's rules, interested parties may file comments on or before April 14, 2003; and reply comments on or before April 28, 2003. All filings should refer to CC Docket No. 96–45. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies.

24. Comments filed through ECFS can be sent as an electronic file via the Internet to <*http://www.fcc.gov/e-file/ecfs.html*>. Generally, only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, Postal Service mailing address, and the applicable docket number, which in this instance is CC Docket No. 96–45. Parties may also submit an electronic comment by Internet e-mail. To receive filing instructions for e-mail comments, commenters should send an e-mail to *ecfs@fcc.gov,* and should include the following words in the body of the message: get form <your e-mail address>. A sample form and directions will be sent in reply.

25. Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, commenters must submit two additional copies for each additional docket or rulemaking number. Parties who choose to file by paper are hereby notified that effective December 18, 2001, the Commission's contractor, Vistronix, Inc., will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at a new location in downtown Washington, DC. The address is 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location will be 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building. This facility is the only location where hand-delivered or messenger-delivered paper filings for

the Commission's Secretary will be accepted. Accordingly, the Commission will no longer accept these filings at 9300 East Hampton Drive, Capitol Heights, MD 20743. Other messenger-delivered documents, including documents sent by overnight mail (other than United States Postal Service (USPS) Express Mail and Priority Mail), must be addressed to 9300 East Hampton Drive, Capitol Heights, MD 20743. This location will be open 8 a.m. to 5:30 p.m. The USPS first-class mail, Express Mail, and Priority Mail should continue to be addressed to the Commission's headquarters at 445 12th Street, SW., Washington, DC 20554. The USPS mail addressed to the Commission's headquarters actually goes to our Capitol Heights facility for screening prior to delivery at the Commission.

| If you are sending this type of document or using this delivery method. . . | It should be addressed for delivery to. . . |
|---|---|
| Hand-delivered or messenger-delivered paper filings for the Commission's Secretary. | 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002 (8 a.m. to 7 p.m.). |
| Other messenger-delivered documents, including documents sent by overnight mail (other than United States Postal Service Express Mail and Priority Mail). | 9300 East Hampton Drive, Capitol Heights, MD 20743 (8 a.m. to 5:30 p.m.). |
| United States Postal Service first-class mail, Express Mail, and Priority Mail. | 445 12th Street, SW., Washington, DC 20554 |

All filings must be sent to the Commission's Secretary: Marlene H. Dortch, Office of the Secretary, Federal Communications Commission, 445 12th Street, SW., Suite TW–A325, Washington, DC 20554.

26. Parties who choose to file by paper should also submit their comments on diskette to Sheryl Todd, Telecommunications Access Policy Division, Wireline Competition Bureau, Federal Communications Commission, 445 12th Street, SW., Room 5–B540, Washington, DC 20554. Such a submission should be on a 3.5 inch diskette formatted in an IBM compatible format using Microsoft Word or compatible software. The diskette should be accompanied by a cover letter and should be submitted in ''read only'' mode. The diskette should be clearly labeled with the commenter's name, proceeding (including the docket number, in this case, CC Docket No. 96–45), type of pleading (comment or reply comment), date of submission, and the name of the electronic file on the diskette. The label should also include the following phrase ''Disk Copy—Not an Original.'' Each diskette should contain only one party's pleading, preferably in a single electronic file. In addition, commenters must send diskette copies to the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554.

27. Regardless of whether parties choose to file electronically or by paper, parties should also file one copy of any documents filed in this docket with the Commission's copy contractor, Qualex International, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street, SW., Washington, DC 20554. In addition, the full text of this document is available for public inspection and copying during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

28. Comments and reply comments must include a short and concise summary of the substantive arguments raised in the pleading. Comments and reply comments must also comply with § 1.49 and all other applicable sections of the Commission's rules. We direct all interested parties to include the name of the filing party and the date of the filing on each page of their comments and reply comments. All parties are encouraged to utilize a table of contents, regardless of the length of their submission. We also strongly encourage parties to track the organization set forth in the NPRM in order to facilitate our internal review process.

*F. Further Information*

29. Alternative formats (computer diskette, large print, audio recording, and Braille) are available to persons with disabilities by contacting Brian Millin at (202) 418–7426 voice, (202) 418–7365 TTY, or *bmillin@fcc.gov.* This NPRM can also be downloaded in Microsoft Word and ASCII formats at *http://www.fcc.gov/ccb/universal_service/highcost.*

**III. Ordering Clauses**

30. Accordingly, it is ordered that, pursuant to the authority contained in sections 4(i), 4(j), 201–205, 214, 254, and 403 of the Communications Act of 1934, as amended, this Notice of Proposed Rulemaking is adopted.

31. It is further ordered that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

**List of Subjects in 47 CFR Part 54**

Reporting and recordkeeping requirements, Telecommunications, Telephone.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

[FR Doc. 03–6092 Filed 3–12–03; 8:45 am]

BILLING CODE 6712–01–P

## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[DA 03–600, Docket No. 02–122, RM–10444]**

## Radio Broadcasting Services; Lone Pine, CA

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule, dismissal.

**SUMMARY:** This document dismisses a pending petition for rulemaking to add an FM allotment in Lone Pine, California. The Audio Division had requested comment on a petition filed by Virgil Todd, proposing the allotment of Channel 249A at Lone Pine, California. *See* 67 FR 41364, June 18, 2002. The Audio Division required petitioner to include, with his comments, verification that the statements contained in the petition are accurate to the best of his knowledge. Petitioner did not file comments supporting the requested allotment. This document dismisses the petition for failure to demonstrate a continuing interest in the requested allotment and for failure to supply the verification required by Section 1.52 of the Commission's rules. See 47 CFR 1.52. The document therefore terminates the proceeding.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Deborah A. Dupont, Media Bureau (202) 418–7072.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Report and Order, MB Docket No. 02–122, adopted February 26, 2003, and released March 4, 2003. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (202) 863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 03–6097 Filed 3–12–03; 8:45 am]

**BILLING CODE 6712–01–P**

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[DA 03–583; MB Docket No. 03–51, RM–10555]**

## Radio Broadcasting Services; Dickson and Pegram, TN

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document sets forth a proposal to amend the FM Table of Allotments, Section 73.202(b) of the Commission's rules, 47 CFR 73.202(b). The Audio Division requests comment on a petition filed by Montgomery Broadcasting Company pursuant to section 1.420(i) of the Commission's rules, 47 CFR 1.420(i). Petitioner proposes to change the community of license for Station WQZQ-FM from Dickson to Pegram, Tennessee, and to change the FM Table of Allotments by deleting Channel 273C1 at Dickson, Tennessee, and by adding Channel 273C1 at Pegram, Tennessee, as the community's first local aural broadcast service. The proposed coordinates for Channel 273C1 at Pegram, Tennessee, are 36–17–50 NL and 87–19–31 WL. The allotment will require a site restriction of 32.9 km (20.5 miles) northwest of Pegram. The change of community from Dickson to Pegram would result in a net loss of 13,341 persons. There would be neither net gain nor loss in the land area served, because the loss and gain area each covers 260 square kilometers. Both the loss area of Channel 273C1 at Dickson and the gain area of Channel 273C1 at Pegram are completely covered by at least five other full-time services, and thus, all areas potentially affected by this proposal would continue to be well-served. Neither Dickson nor Pegram is located within an urbanized area. The existing 70 dBu signal for WQZQ-FM at Dickson covers 100 percent of the Clarksville, Tennessee-Kentucky Urbanized Area and 25.2 percent of the Nashville-Davidson, Tennessee Urbanized Area. The 70 dBu contour of the proposed Channel 273C1 facility at Pegram would cover 100 percent of the Clarksville, Tennessee-Kentucky Urbanized Area and 20.3 percent of the Nashville-Davidson, Tennessee Urbanized Area. Under the circumstances described in the petition, no *Tuck* analysis will be necessary to evaluate this change of community proposal.

**DATES:** Comments must be filed on or before April 25, 2003, and reply comments on or before May 12, 2003.

**ADDRESSES:** Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the petitioner as follows: John F. Garziglia, Mark Blacknell, Womble, Carlyle, Sandridge & Rice, PLLC, 1776 K Street, NW., Suite 200, Washington, DC 20036.

**FOR FURTHER INFORMATION CONTACT:** Deborah A. Dupont, Media Bureau (202) 418–7072.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 03–51; adopted February 26, 2003 and released March 4, 2003. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center (Room CY–A257), 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (202)863–2893, facsimile (202) 863–2898, or via e-mail *qualexint@aol.com.*

The Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

### List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for Part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.202 [Amended]**

2. Section 73.202(b), the Table of FM Allotments under Tennessee, is amended by removing Dickson, Channel 273C and by adding Pegram, Channel 273C.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 03–6096 Filed 3–12–03; 8:45 am]

**BILLING CODE 6712–01–P**

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[DA 03–584; MB Docket No. 03–52, RM–10657; MB Docket No. 03–53, RM–10658; MB Docket No. 03–54, RM–10659]**

## Radio Broadcasting Services; Dalhart, Kermit, and Leakey, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document proposes three new allotments in Dalhart, Kermit, and Leakey, Texas. The Audio Division requests comment on a petition filed by Linda Crawford proposing the allotment of Channel 261C at Dalhart, Texas, as the community's second FM commercial aural transmission service. Channel 261C can be allotted to Dalhart in compliance with the Commission's minimum distance separation requirements with a site restriction of 38.6 kilometers (24 miles) northwest to avoid a short-spacing to the license site of Station KOMX, Channel 262C2,

Pampa, Texas. The reference coordinates for Channel 261C at Dalhart are 36–14–36 North Latitude and 102–52–36 West Longitude. *See* **SUPPLEMENTARY INFORMATION,** *infra.*

**DATES:** Comments must be filed on or before April 25, 2003, and reply comments on or before May 12, 2003.

**ADDRESSES:** Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, his counsel, or consultant, as follows: Linda Crawford, 3500 Maple Avenue #1320, Dallas, TX 75219; Al Boyd, 3607 Thomason, Midland, Texas 79703; and Katherine Pyeatt, 6655 Aintree Circle, Dallas, Texas 75214.

**FOR FURTHER INFORMATION CONTACT:** Rolanda F. Smith, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket Nos. 03–52, 03–53, 03–54, adopted February 26, 2003, and released March 4, 2003. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via e-mail *qualexint@aol.com.*

The Audio Division requests comments on a petition filed by Al Boyd proposing the allotment of Channel 229A at Kermit, Texas, as the community's second FM commercial aural transmission service. Channel 229A can be allotted to Kermit in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The reference coordinates for Channel 229A at Kermit are 31–51–27 North Latitude and 103–05–32 West Longitude. Since Kermit is located within 320 kilometers (199 miles) of the U.S.-Mexican border, concurrence of the Mexican government has been requested.

The Audio Division requests comments on a petition filed by Katherine Pyeatt proposing the allotment of Channel 257A at Leakey, Texas, as the community's fifth local aural transmission service. Channel 257A can be allotted to Leakey in compliance with the Commission's minimum distance separation requirements with a site restriction 11.4 kilometers (7.1 miles) west of the community. The reference coordinates for Channel 257A at Leakey are 29–44–41 North Latitude and 99–52–40 West Longitude. Since Leakey is located within 320 kilometers (199 miles) of the U.S.-Mexican border, concurrence of the Mexican government has been requested.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Radio, Radio broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

### § 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Channel 261C at Dalhart; by adding Channel 229A at Kermit; by adding Channel 257A at Leakey.

Federal Communications Commission.

**John A. Karousos,**

*Assistant Chief, Audio Division, Media Bureau.*

[FR Doc. 03–6093 Filed 3–12–03; 8:45 am]

BILLING CODE 6712–01–P

# Notices

Federal Register

Vol. 68, No. 49

Thursday, March 13, 2003

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

### Agricultural Marketing Service

**[Doc. No. FV03–932–2 NC]**

### Notice of Request for Extension of a Currently Approved Information Collection

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Agricultural Marketing Service's (AMS) intention to request an extension for a currently approved information collection for Olives Grown in California, Marketing Order 932.

**DATES:** Comments on this notice must be received by May 12, 2003, to be assured of consideration.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this notice. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250–0237; Fax: (202) 720–8938, or E-mail: *moab.docketclerk@usda.gov.* All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http:/ www.ams.usda.gov/fv/moab.html.*

**FOR FURTHER INFORMATION CONTACT:** Caroline Thorpe, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491; Fax: (202) 720–8938.

Small businesses may request information on this notice by contacting Jay Guerber, Regulatory Fairness Representative, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., Stop 0237, Washington, DC 20250–0237; telephone (202) 720–2491, Fax: (202) 720–8938, or E-mail: *Jay.Guerber@usda.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Olives Grown in California, Marketing Order 932.

*OMB Number:* 0581–0142.

*Expiration Date of Approval:* September 30, 2003.

*Type of Request:* Extension of a currently approved information collection.

*Abstract:* Marketing order programs provide an opportunity for producers of fresh fruits, vegetables, and specialty crops, in a specified production area, to work together to solve marketing problems that cannot be solved individually. Order regulations help ensure adequate supplies of good quality product and adequate returns to producers. Under the Agricultural Marketing Agreement Act of 1937 (Act), as amended (7 U.S.C. 601–674), marketing order programs are established if favored by producers in referenda. The handling of the commodity is regulated. The Secretary of Agriculture is authorized to oversee order operations and issue regulations recommended by a committee of representatives from each commodity industry.

The information collection requirements in this request are essential to carry out the intent of the Act, to provide the respondents the type of service they request, and to administer the California olive marketing order program, which has been operating since 1965.

The California olive marketing order authorizes the issuance of quality, size, and inspection requirements. The order also has authority for research and development projects, including paid advertising. Pursuant to section 8e of the Act, import grade and size requirements are implemented on olives imported into the United States.

The order and its rules and regulations authorize the California Olive Committee (committee), the agency responsible for local administration of the order, to require handlers and producers to submit certain information. Much of this information is compiled in aggregate and provided to the industry to assist in marketing decisions.

The committee has developed forms as a means for persons to file required information with the committee relating to olive supplies, shipments, dispositions, and other information necessary to effectively carry out the purpose of the Act and the order. California olives are shipped year-round and these forms are used accordingly. A USDA form is used to allow growers to vote on amendments to or continuance of the order.

Formal rulemaking amendments to the order must be approved in referenda conducted by the Secretary. Also, the Secretary may conduct a continuance referendum to determine industry support for continuation of the order. Handlers are asked to sign an agreement to indicate their willingness to abide by the provisions of the order whenever the order is amended. These forms are included in this request.

All the forms under this program require the minimum information necessary to effectively carry out the requirements of the order, and their use is necessary to fulfill the intent of the Act as expressed in the order.

The information collected would be used only by authorized representatives of the USDA, including AMS, Fruit and Vegetable Programs' regional and headquarter's staff, and authorized employees of the committee. Authorized committee employees and the industry are the primary users of the information and AMS is the secondary user.

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average .28 hour per response.

*Respondents:* California olive handlers and growers.

*Estimated Number of Respondents:* 691.

*Estimated Number of Responses per Respondent:* 15.

*Estimated Total Annual Burden on Respondents:* 2947 hours.

The information collection burden would affect both California olive growers and handlers. The majority of the collection burden consists of Weight and Grade Reports totaling an estimated 2,250 burden hours. These reports are filed by handlers, who like growers,

benefit from improved returns due to more orderly market conditions. The rest of this information collection consists of twenty-four forms that add a total of 697 estimated burden hours.

*Comments are invited on:* (1) Whether the proposed collection of the information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) 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) 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 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.

Comments should reference OMB No. 0581–0142 and California Olive Marketing Order No. 932, and be sent to Docket Clerk, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or E-mail: *moab.docketclerk@usda.gov.* All comments received will be available for public inspection during regular business hours at the same address and will become a matter of public record.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: March 7, 2003.

**A. J. Yates,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 03–5970 Filed 3–12–03; 8:45 am]

**BILLING CODE 3410–02–P**

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## DEPARTMENT OF AGRICULTURE

### Economic Research Service

### Notice of Intent To Seek Approval To Collect Information

**AGENCY:** Economic Research Service, USDA.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (Pub L. 104–13) and Office of Management and Budget (OMB) regulations at 5 CFR Part 1320 (60 FR 44978, August 29, 1995), this notice announces the Economic Research Service's (ERS) intention to request approval for a new information collection from the U.S. population. The study will collect information from Food Stamp Program (FSP) participants that reside in one of six demonstration sites.

**DATES:** Written comments must be received by May 19, 2003 to be assured of consideration.

**ADDRESSES:** Requests for additional information regarding this notice should be directed to Elizabeth Dagata, Rural Economy Branch, Food and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture, 1800 M St. NW., Washington, DC 20036–5831. Submit electronic comments to *edagata@ers.usda.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Evaluation of Three Models Designed to Increase Participation of Eligible Elderly in the Food Stamp Program.

*OMB Number:* Not yet assigned.

*Expiration Date:* Two years from date of issuance.

*Type of Request:* Approval to collect information from elderly individuals who receive food stamps and who reside in one of the Elderly Nutrition Demonstration pilot sites.

*Abstract:* USDA's Economic Research Service (ERS) has the responsibility to provide social and economic intelligence on consumer, food marketing, and rural issues, including food security status of the poor; domestic food assistance programs; low-income assistance programs; economic food consumption determinations and trends; consumer demand for food quality, safety, and nutrition; food market competition and coordination; and food safety regulation. In carrying out this overall mission, ERS seeks approval of information gathering activities that will provide key information about the impact of the Food Stamp Program's (FSP) Elderly Nutrition Demonstration pilots.

Six states (Arizona, Connecticut, Florida, Maine, Michigan, and North Carolina) are implementing separate Elderly Nutrition Demonstration pilots, with each State's pilot based on one of three demonstration models: (1) A commodities alternative benefit model, in which elderly FSP participants can elect to receive a package of commodities each month in lieu of traditional FSP benefits; (2) a simplified eligibility model, in which the FSP eligibility rules for elderly applicants are streamlined; or (3) an application assistance model, in which demonstration staff assist elderly FSP applicants with completing the food stamp application. Two states (Connecticut and North Carolina) are implementing a commodities alternative benefit model; one state (Florida) is implementing a simplified eligibility model; and three states (Arizona, Maine and Michigan) are implementing an application assistance model. USDA is operating these pilot projects to explore which demonstration models lead to increased participation among elderly individuals in the Food Stamp Program and why.

Working with ERS, a contractor will be evaluating the six demonstration models. Participation data obtained through administrative case records will be used to estimate the impact of the demonstrations on the number of elderly participants in the Food Stamp Program. To identify reasons why elderly individuals may be more likely to participate under the demonstrations, the contractor will contact elderly Food Stamp Program participants directly.

In the two states that are implementing the commodities alternative benefit demonstration model (Connecticut and North Carolina), a sample of elderly food stamp participants will be surveyed. The survey will query respondents as to whether or not they chose to participate in the commodity alternative benefit demonstration, the reason for that choice, and, if they are receiving the commodity alternative benefit, what they like and dislike about it. A different sample of respondents will be identified every quarter, and interviews will occur between three and seven quarters. A small sub-sample of respondents will be contacted a second time to acquire more detailed information about their experience with the demonstration.

In addition to the survey conducted in the two commodities demonstration sites, focus groups will be conducted in the one state implementing the simplified eligibility demonstration model (Florida) and in the three states implementing the application assistance demonstration model (Arizona, Maine and Michigan). There will be two focus groups per state, with each focus group including 10 elderly FSP participants. These focus groups will be used to determine what aspects of each demonstration were beneficial to the clients.

*Affected Public:* Elderly FSP participants residing in the demonstration sites.

*Estimated Number of Respondents:* A combined total of 167 individuals in the two commodities alternative benefit demonstration sites will be interviewed per quarter, and interviews will be conducted for three to seven quarters. The maximum number of interviews conducted is 1,169 (= 167 respondents × 7 quarters). In the remaining four

demonstration sites, a combined total of 80 individuals will participate in focus groups (10 participants per focus group × 2 focus groups × 4 states).

*Number of Responses per Respondent:* Of the individuals participating in the initial interview, a total of 36 individuals will respond twice (once to the initial interview and once to the follow-up interview). The remaining individuals (up to 1,133) will respond only once. The 80 individuals participating in the focus groups will respond once.

*Estimated Total Responses:* Maximum total number of responses: 1,285 (= 1,169 initial commodities interviews + 36 follow up interviews + 80 focus group participants).

*Hours per Response:* Initial commodities alternative benefit interview: 20 minutes per respondent; follow-up commodities alternative benefit interview: 20 minutes per respondent; focus group: 1 hour 15 minutes per respondent.

*Total Reporting Hours:* Maximum total reporting hours: 498 hours (= 1,169 initial commodities interviews * 0.33 hours + 36 follow up interviews * 0.33 hours + 80 focus group participants * 1.25 hours).

*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 has practical utility; (b) 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) 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 the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to the address stated in the preamble. All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will also become a matter of public record.

Dated: February 25, 2003.

**Susan Offut,**

*Administrator, Economic Research Service, USDA.*

[FR Doc. 03–6056 Filed 3–12–03; 8:45 am]

BILLING CODE 3410–18–P

## DEPARTMENT OF AGRICULTURE

### Food and Nutrition Service

### Child Nutrition Programs—Income Eligibility Guidelines

**AGENCY:** Food and Nutrition Service, USDA.

**ACTION:** Notice.

**SUMMARY:** This Notice announces the Department's annual adjustments to the Income Eligibility Guidelines to be used in determining eligibility for free and reduced price meals or free milk for the period from July 1, 2003 through June 30, 2004. These guidelines are used by schools, institutions, and facilities participating in the National School Lunch Program (and Commodity School Program), School Breakfast Program, Special Milk Program for Children, Child and Adult Care Food Program and Summer Food Service Program. The annual adjustments are required by section 9 of the Richard B. Russell National School Lunch Act. The guidelines are intended to direct benefits to those children most in need and are revised annually to account for changes in the Consumer Price Index.

**EFFECTIVE DATE:** July 1, 2003.

**FOR FURTHER INFORMATION CONTACT:** Mr. Robert M. Eadie, Chief, Policy and Program Development Branch, Child Nutrition Division, FNS, USDA, Alexandria, Virginia 22302, or by phone at (703) 305–2620.

**SUPPLEMENTARY INFORMATION:** This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This action is exempted from review by the Office of Management and Budget under Executive Order 12866.

These programs are listed in the Catalog of Federal Domestic Assistance under No. 10.553, No. 10.555, No. 10.556, No. 10.558 and No. 10.559 and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR Part 3015, Subpart V, and the final rule related notice published at 48 FR 29114, June 24, 1983.)

### Background

Pursuant to sections 9(b)(1) and 17(c)(4) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1758(b)(1) and 42 U.S.C. 1766(c)(4)), and sections 3(a)(6) and 4(e)(1)(A) of the Child Nutrition Act of 1966 (42 U.S.C. 1772(a)(6) and 1773(e)(1)(A)), the Department annually issues the Income Eligibility Guidelines for free and reduced price meals for the National School Lunch Program (7 CFR Part 210), the Commodity School Program (7 CFR Part 210), School Breakfast Program (7 CFR Part 220), Summer Food Service Program (7 CFR Part 225) and Child and Adult Care Food Program (7 CFR Part 226) and the guidelines for free milk in the Special Milk Program for Children (7 CFR Part 215). These eligibility guidelines are based on the Federal income poverty guidelines and are stated by household size. The guidelines are used to determine eligibility for free and reduced price meals and free milk in accordance with applicable program rules.

### Definition of Income

In accordance with the Department's policy as provided in the Food and Nutrition Service publication *Eligibility Guidance for School Meals Manual,* ''income,'' as the term is used in this Notice, means income before any deductions such as income taxes, Social Security taxes, insurance premiums, charitable contributions and bonds. It includes the following: (1) Monetary compensation for services, including wages, salary, commissions or fees; (2) net income from nonfarm self-employment; (3) net income from farm self-employment; (4) Social Security; (5) dividends or interest on savings or bonds or income from estates or trusts; (6) net rental income; (7) public assistance or welfare payments; (8) unemployment compensation; (9) government civilian employee or military retirement, or pensions or veterans payments; (10) private pensions or annuities; (11) alimony or child support payments; (12) regular contributions from persons not living in the household; (13) net royalties; and (14) other cash income. Other cash income would include cash amounts received or withdrawn from any source including savings, investments, trust accounts and other resources that would be available to pay the price of a child's meal.

''Income,'' as the term is used in this Notice, does not include any income or benefits received under any Federal programs that are excluded from consideration as income by any legislative prohibition. Furthermore, the value of meals or milk to children shall not be considered as income to their households for other benefit programs in accordance with the prohibitions in

section 12(e) of the Richard B. Russell National School Lunch Act and section 11(b) of the Child Nutrition Act of 1966 (42 U.S.C. 1760(e) and 1780(b)).

**The Income Eligibility Guidelines**

The following are the Income Eligibility Guidelines to be effective from July 1, 2003 through June 30, 2004. The Department's guidelines for free meals and milk and reduced price meals were obtained by multiplying the year 2003 Federal income poverty guidelines by 1.30 and 1.85, respectively, and by rounding the result upward to the next whole dollar. Weekly and monthly guidelines were computed by dividing annual income by 52 and 12, respectively, and by rounding upward to the next whole dollar. The numbers reflected in this notice for a family of four represent an increase of 1.66% over the July 2002 numbers for a family of the same size.

BILLING CODE 3410–30–P

INCOME ELIGIBILITY GUIDELINES
(Effective from July 1, 2003 to June 30, 2004)

| Household size | Federal Poverty Guidelines | | | Reduced Price Meals - 185% | | | Free Meals - 130% | | |
|---|---|---|---|---|---|---|---|---|---|
| | Annual | Month | Week | Annual | Month | Week | Annual | Month | Week |
| 48 CONTIGUOUS UNITED STATES, DISTRICT OF COLUMBIA, GUAM AND TERRITORIES | | | | | | | | | |
| 1 | 8,980 | 749 | 173 | 16,613 | 1,385 | 320 | 11,674 | 973 | 225 |
| 2 | 12,120 | 1,010 | 234 | 22,422 | 1,869 | 432 | 15,756 | 1,313 | 303 |
| 3 | 15,260 | 1,272 | 294 | 28,231 | 2,353 | 543 | 19,838 | 1,654 | 382 |
| 4 | 18,400 | 1,534 | 354 | 34,040 | 2,837 | 655 | 23,920 | 1,994 | 460 |
| 5 | 21,540 | 1,795 | 415 | 39,849 | 3,321 | 767 | 28,002 | 2,334 | 539 |
| 6 | 24,680 | 2,057 | 475 | 45,658 | 3,805 | 879 | 32,084 | 2,674 | 617 |
| 7 | 27,820 | 2,319 | 535 | 51,467 | 4,289 | 990 | 36,166 | 3,014 | 696 |
| 8 | 30,960 | 2,580 | 596 | 57,276 | 4,773 | 1,102 | 40,248 | 3,354 | 774 |
| For each add'l family member add | +3,140 | +262 | +61 | +5,809 | +485 | +112 | +4,082 | +341 | +79 |
| ALASKA | | | | | | | | | |
| 1 | 11,210 | 935 | 216 | 20,739 | 1,729 | 399 | 14,573 | 1,215 | 281 |
| 2 | 15,140 | 1,262 | 292 | 28,009 | 2,335 | 539 | 19,682 | 1,641 | 379 |
| 3 | 19,070 | 1,590 | 367 | 35,280 | 2,940 | 679 | 24,791 | 2,066 | 477 |
| 4 | 23,000 | 1,917 | 443 | 42,550 | 3,546 | 819 | 29,900 | 2,492 | 575 |
| 5 | 26,930 | 2,245 | 518 | 49,821 | 4,152 | 959 | 35,009 | 2,918 | 674 |
| 6 | 30,860 | 2,572 | 594 | 57,091 | 4,758 | 1,098 | 40,118 | 3,344 | 772 |
| 7 | 34,790 | 2,900 | 670 | 64,362 | 5,364 | 1,238 | 45,227 | 3,769 | 870 |
| 8 | 38,720 | 3,227 | 745 | 71,632 | 5,970 | 1,378 | 50,336 | 4,195 | 968 |
| For each add'l family member add | +3,930 | +328 | +76 | +7,271 | +606 | +140 | +5,109 | +426 | +99 |
| HAWAII | | | | | | | | | |
| 1 | 10,330 | 861 | 199 | 19,111 | 1,593 | 368 | 13,429 | 1,120 | 259 |
| 2 | 13,940 | 1,162 | 269 | 25,789 | 2,150 | 496 | 18,122 | 1,511 | 349 |
| 3 | 17,550 | 1,463 | 338 | 32,468 | 2,706 | 625 | 22,815 | 1,902 | 439 |
| 4 | 21,160 | 1,764 | 407 | 39,146 | 3,263 | 753 | 27,508 | 2,293 | 529 |
| 5 | 24,770 | 2,065 | 477 | 45,825 | 3,819 | 882 | 32,201 | 2,684 | 620 |
| 6 | 28,380 | 2,365 | 546 | 52,503 | 4,376 | 1,010 | 36,894 | 3,075 | 710 |
| 7 | 31,990 | 2,666 | 616 | 59,182 | 4,932 | 1,139 | 41,587 | 3,466 | 800 |
| 8 | 35,600 | 2,967 | 685 | 65,860 | 5,489 | 1,267 | 46,280 | 3,857 | 890 |
| For each add'l family member add | +3,610 | +301 | +70 | +6,679 | +557 | +129 | +4,693 | +392 | +91 |

**Authority:** (42 U.S.C. 1758(b)(1)).

Dated: March 6, 2003.

**Roberto Salazar,**

*Administrator.*

[FR Doc. 03–6079 Filed 3–12–03; 8:45 am]

**BILLING CODE 3410–30–C**

## DEPARTMENT OF AGRICULTURE

### National Agricultural Statistics Service

### Notice of Intent To Seek Approval To Conduct an Information Collection

**AGENCY:** National Agricultural Statistics Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 (Public Law 104–13) and Office of Management and Budget regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the intention of the National Agricultural Statistics Service (NASS) to request approval to conduct a new information collection, the Conservation Effects Assessment Survey.

**DATES:** Comments on this notice must be received by May 19, 2003 to be assured of consideration.

**ADDRESSES:** Comments may be mailed to Ginny McBride, NASS OMB Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250 or sent electronically to *gmcbride@nass.usda.gov.*

**FOR FURTHER INFORMATION CONTACT:** Carol House, Acting Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333.

**SUPPLEMENTARY INFORMATION:**

*Title:* Conservation Effects Assessment Survey.

*Type of Request:* Intent to Seek Approval to Conduct a New Information Collection.

*Abstract:* The primary objective of the National Agricultural Statistics Service is to prepare and issue State and national estimates of crop and livestock production, prices, and disposition. The goal of this NASS project is to collect land management information that will assist the Natural Resources Conservation Service (NRCS) in assessing environmental benefits associated with implementation of various conservation programs and installation of associated conservation practices. The 2002 Farm Bill substantially increased funding for the Environmental Quality Incentives Program (EQIP) as well as other conservation programs; a portion of the technical assistance funds for conservation programs has been allocated for use in assessing the environmental benefits of these conservation practices. The assessment will be used to report progress annually on Farm Bill implementation to Congress and the general public. The information collected will also be used to provide OMB with requested information on the cost effectiveness of the EQIP and the Conservation Reserve Program.

NRCS has been given the responsibility of leading a multi-agency effort to estimate the environmental benefits of conservation practices. Benefit measures will initially include soil quality enhancement, erosion reduction, reduction in nutrient and sediment losses from farm fields, soil carbon sequestration, water use efficiency, and reductions in in-stream nutrient and sediment concentrations. Investments are being made in additional model development to address benefits associated with reductions in pesticide losses, air quality, and wildlife habitat. The assessment is designed to be national and regional in scope. A sampling and modeling approach has been adopted to avoid the high costs associated with expanded reporting by NRCS field staff.

Benefits will be estimated by applying transport models and other physical process models at sample sites associated with the National Resources Inventory (NRI) sampling frame. The NRI is a scientifically-based, longitudinal panel survey designed to assess conditions and trends of soil, water, and related resources of the Nation's non-federal lands. The NRI is conducted for the U.S. Department of Agriculture by NRCS in cooperation with the Iowa State University Statistical Laboratory and provides critical information to address agri-environmental issues at national, regional, and State levels. Data gathered in the NRI are linked to NRCS soil survey and climate databases. These linked data, along with NRI's historical data for 1982–2001, form the basis for unique modeling applications and analytical capabilities. The NRI sampling frame will be used for this project because it captures the diversity of the Nation's agricultural resource base (soils, topography, and climate), which is a critical factor in estimating benefits of conservation practices. Also critical are the historical and linked data that already exist for each NRI sample site. The assessment of benefits is not possible, however, without augmenting these existing data with additional information on land management and conservation practice adoption.

NASS will collaborate with NRCS in the acquisition of this additional information by conducting a survey for a sub-sample of NRI sample units in the contiguous 48 States. The survey will utilize personal interviews to administer a questionnaire that is designed to obtain from farm operators field-specific data associated with the selected sample units. Specific questions are asked about physical characteristics of the field and technical aspects of conservation practices associated with the field. Several other questions deal with production activities before and after implementation of specific conservation practice and with the operator's participation in conservation programs. The survey will be conducted in the fall of each year beginning in 2003 and extending through 2008, which is the last year covered by the 2002 Farm Bill. Approximately 15,000–20,000 interviews will be conducted each year. Each year's data collection will be for a different set of agricultural land units. The scope of the study will broaden as the models are extended to cover a broader suite of conservation practices and effects. These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents.

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 60 minutes per response.

*Respondents:* Farm operators.

*Estimated Number of Respondents:* 18,000.

*Estimated Total Annual Burden on Respondents:* 18,000 hours.

Copies of this information collection and related instructions can be obtained without charge from Ginny McBride, NASS OMB Clearance Officer, at (202) 720–5778.

*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 will have practical utility; (b) 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) 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 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.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, February 13, 2003.

**Carol House,**

*Acting Associate Administrator.*

[FR Doc. 03–6057 Filed 3–12–03; 8:45 am]

BILLING CODE 3410–20–P

## DEPARTMENT OF AGRICULTURE

### Rural Business-Cooperative Service

### Maximum Portion of Guarantee Authority Available for Fiscal Year 2003

**AGENCY:** Rural Business-Cooperative Service, USDA.

**ACTION:** Notice.

**SUMMARY:** As set forth in 7 CFR part 4279, subpart B, each fiscal year (FY) the Agency shall establish a limit on the maximum portion of guarantee authority available for that fiscal year that may be used to guarantee loans with a guarantee fee of 1 percent or guaranteed loans with a guarantee percentage exceeding 80 percent. This notice covers only FY 2002 carryover and recovered funds. Once FY 2003 appropriated funds are apportioned, a second notice will be published for those funds.

Allowing the guarantee fee to be reduced to 1 percent or exceeding the 80 percent guarantee on certain guaranteed loans that meet the conditions set forth in 7 CFR 4279.107 and 4279.119 will increase the Agency's ability to focus guarantee assistance on projects which the Agency has found particularly meritorious, such as projects in rural communities that remain persistently poor, experience long-term population decline and job deterioration, are experiencing trauma as a result of natural disaster or are experiencing fundamental structural changes in the economic base.

Not all of the available Business and Industry (B&I) Guaranteed Loan program funding authority for FY 2002 was used; consequently, this and recovered funding authority for approved B&I Guaranteed Loans which did not come to fruition are now apportioned and available for use. Not more than 12 percent of the Agency's quarterly apportioned carryover and recovered guarantee authority will be reserved for loan requests with a guarantee fee of 1 percent, and not more than 15 percent of the Agency quarterly apportioned carryover and recovered guarantee authority will be reserved for guaranteed loan requests with a guaranteed percentage exceeding 80 percent. Once the above quarterly limits have been reached, all additional loans guaranteed with carryover and recovered funds during the remainder of that quarter will require a 2 percent guarantee fee and not exceed an 80 percent guarantee limit. As an exception to this paragraph and for the purposes of this notice, loans developed by the North American Development Bank (NADBank) Community Adjustment and Investment Program (CAIP) will not count against the 15 percent limit. Up to 50 percent of CAIP funds may be used for loan requests with a guaranteed percentage exceeding 80 percent.

Written requests by the Rural Development State Office for approval of a guaranteed loan with a 1 percent guarantee fee or a guaranteed loan exceeding 80 percent must be forwarded to the National Office, Attn: Director, Business and Industry Division, for review and consideration prior to obligation of the guaranteed loan. The Administrator will provide a written response to the State Office confirming approval or disapproval of the request.

**EFFECTIVE DATE:** March 13, 2003.

**FOR FURTHER INFORMATION CONTACT:** Fred Kieferle, Processing Branch Chief, Business and Industry Division, Rural Business-Cooperative Service, USDA, Stop 3224, 1400 Independence Avenue, SW., Washington, DC 20250–3224, telephone (202) 720–7818.

**SUPPLEMENTARY INFORMATION:** This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866.

Dated: March 4, 2003.

**John Rosso,**

*Administrator, Rural Business-Cooperative Service.*

[FR Doc. 03–6052 Filed 3–12–03; 8:45 am]

BILLING CODE 3410–XY–P

## DEPARTMENT OF AGRICULTURE

### Rural Housing Service

### Notice of Request for Collection of Public Information With the Use of a Survey

**AGENCY:** Rural Housing Service, USDA.

**ACTION:** Proposed collection; comments requested.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Housing Service's intention to request clearance for a new information collection to measure the quality of service provided by the Rural Housing Service (RHS) Centralized Servicing Center (CSC).

**DATES:** Comments on this notice must be received by May 12, 2003, to be assured of consideration.

**FOR FURTHER INFORMATION CONTACT:** Bill Scaggs, Section Head, Customer Service Branch, Centralized Servicing Center, 1520 Market Street, Room 3622, St. Louis, Missouri 63103, phone: (314) 206–2096, e-mail: *bs244@stl.rural.usda.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Rural Housing Service—Customer Satisfaction Survey.

*Type of Request:* New information collection.

*Abstract:* The Rural Housing Service (RHS) provides insured loans to low- and moderate-income applicants located in rural geographic areas to assist them in obtaining decent, sanitary, and safe dwellings. RHS currently processes loan originations through approximately 900 Field Offices. The RHS Centralized Servicing Center (CSC), located in St. Louis, Missouri, provides support to the Field Offices and is responsible for loan servicing functions with borrowers. The CSC was established to achieve a high level of customer service and operating efficiency. The CSC has established a fully integrated call center and is able to provide borrowers with convenient access to their loan account information.

To facilitate the CSC's mission and in an effort to continuously improve its services, a survey has been developed that can measure the quality of service that the Field Offices and borrowers receive when they contact the CSC. Respondents will only need to report information on a one-time basis. The outcome of the Customer Satisfaction Survey will provide the general satisfaction level among RHS customers throughout the nation highlighting areas that need improvement and to provide a benchmark for future surveys and improvements in customer service. A follow up survey will be conducted in 18 months, but may or may not be sent to the same initial respondents. Additionally, in accordance with Government Performance and Results Act (GPRA), the survey will enable CSC to measure the results and overall effectiveness of customer services

provided as well as implement action plans and measure improvements.

*Estimate of Burden:* Public reporting burden for this collection of information is estimated to average 10 minutes per response.

*Respondents:* Field office personnel, most likely office clerks and borrowers.

*Estimated Number of Respondents:* 23,000.

*Estimated Number of Responses per Respondent:* 1.

*Estimated Number of Responses:* 23,000

*Estimated Total Annual Burden on Respondents:* 3,680

Copies of this information collection can be obtained from Cheryl Thompson, Regulations and Paperwork Management Branch, Support Services Division at (202) 692–0043.

*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 will have practical utility; (b) the accuracy of agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (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 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. Comments may be sent to Cheryl Thompson, Regulations and Paperwork Management Branch, Support Services Division, U.S. Department of Agriculture, Rural Development, STOP 0742, 1400 Independence Ave., SW., Washington, DC 20250–0742. All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: March 6, 2003.

**Arthur A. Garcia,**

*Administrator, Rural Housing Service.*

[FR Doc. 03–6053 Filed 3–12–03; 8:45 am]

BILLING CODE 3410–XY–P

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

DOC has submitted 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:* Questionnaire for Building Permit Officials.

*Form Number(s):* SOC–QBPO.

*Agency Approval Number:* 0607–0125.

*Type of Request:* Extension of a currently approved collection.

*Burden:* 225 hours.

*Number of Respondents:* 900.

*Avg Hours Per Response:* 15 minutes.

*Needs and Uses:* The Census Bureau requests an extension of the current OMB clearance of the Questionnaire for Building Permit Officials (SOC–QBPO). The Census Bureau uses the SOC–QBPO to collect information from state and local building permit officials, such as (1) The types of permits they issue, (2) the length of time a permit is valid, (3) how they store the permits, and (4) the geographic coverage of the permit system. Census Bureau field representatives visit selected permit-issuing places and conduct the survey using Computer-Assisted Personal Interviewing (CAPI) technology and a lap top computer. We need this information to carry out the sampling for the Survey of Housing Starts, Sales and Completions (OMB number 0607–0110), also known as the Survey of Construction (SOC). The SOC provides widely used measures of construction activity, including the economic indicators Housing Starts, Housing Completions, and New Housing Sales.

We plan no changes to the information collection.

*Affected Public:* Businesses or other for-profit.

*Frequency:* Annually.

*Respondent's Obligation:* Voluntary.

*Legal Authority:* Title 13 U.S.C., section 182.

*OMB Desk Officer:* Susan Schechter, (202) 395–5103.

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 Susan Schechter, OMB Desk Officer either by fax (202–395–7245) or email (*susan_schechter@omb.eop.gov*).

Dated: March 7, 2003.

**Madeleine Clayton,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 03–5966 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–07–P

## DEPARTMENT OF COMMERCE

### Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted 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:* Chemical Weapons Convention Declaration Forms.

*Agency Form Number:* Form 1–1, Form 1–2, Form 1–2A, Form 1–2B, etc.

*OMB Approval Number:* 0694–0091.

*Type of Request:* Renewal of a currently approved collection.

*Burden:* 20,538 hours.

*Average Time Per Response:* 10 minutes–31 hours per response.

*Number of Respondents:* 929 respondents.

*Needs and Uses: Declarations:* The CWC requires annual declarations and reports for activities involving Schedule 1, Schedule 2, Schedule 3 and Unscheduled Discrete Organic Chemicals (UDOCs) above specified threshold quantities. The frequency of this collection is the minimum required under the CWC. The associated Declaration and Report Handbooks and the forms are available from the following Internet URL: *http://www.cwc.gov/Declarations/Handbooks_and_Forms/cwcIndex_html*

*Schedule 1:* The CWC requires annual declarations for facilities that produced in excess of specified aggregate quantities of Schedule 1 chemicals in the previous calendar year.

*Schedule 2:* The CWC requires plant sites that had one or more plants that produced, processed or consumed Schedule 2 chemicals above the applicable threshold quantity during any of the three previous to determine whether there is an annual declaration requirement on past activities.

*Schedule 3:* The CWC requires annual declarations from plant sites that had one or more plants that produced in excess of specified quantities of one or more Schedule 3 chemicals in the previous calendar year.

*UDOCs:* Although the majority of declarations are required from plant

sites that produced UDOCs, the declaration requirements for such production involve the fewest forms. The CWC only requires declarations from plant sites that produced UDOCs in excess of specified quantities in the previous calendar year.

BIS officials review the information collected from the data declarations for completeness and accuracy. The data is then compiled into a report for transmittal to the U.S. National Authority (USNA) and subsequent presentation to the Organization for the Prohibition of Chemical Weapons (OPCW). The collected data will also be used by BIS officials to monitor the aggregate amount of Schedule 1 chemicals in the United States to ensure that it is at all times below 1 metric ton (as required by Part VI.A.2 of the Convention's Annex on Implementation and Verification), and to prepare such additional reports as the USNA may reasonably require.

*Inspections:* Each State Party to the CWC, including the United States Government, has agreed to allow inspections of certain declared facilities by inspectors employed by the OPCW to ensure that their activities are consistent with obligations under the CWC. The Department of Commerce is responsible for leading, hosting and escorting inspections of all facilities in the United States, except Department of Defense and Department of Energy facilities and other United States Government facilities that notify the USNA of their decision to be excluded from the CWCR.

*Affected Public:* Individuals, businesses or other for-profit institutions.

*Respondent's Obligation:* Mandatory.

*OMB Desk Officer:* David Rostker.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, DOC Paperwork Clearance Officer, Office of the Chief Information 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, Room 10202, New Executive Office Building, Washington, DC 20230.

Dated: March 7, 2003.

**Madeleine Clayton,**

*Departmental Paperwork Clearance Officer, Office of the Chief Information Officer.*

[FR Doc. 03–5967 Filed 3–12–03; 8:45 am]

**BILLING CODE 3510–33–P**

## DEPARTMENT OF COMMERCE

### Census Bureau

### Annual Survey of Manufacturers

**ACTION:** Proposed collection; comment request.

**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:** Written comments must be submitted on or before May 12, 2003.

**ADDRESSES:** Direct all written 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 Mendel D. Gayle, Census Bureau, Room 2108, Building 4, Washington, DC 20233, (301) 763–4769 or via the Internet at *mendel.d.gayle@census.gov.*

**SUPPLEMENTARY INFORMATION**

### I. Abstract

The Census Bureau has conducted the Annual Survey of Manufacturers (ASM) since 1949 to provide key measures of manufacturing activity during intercensal periods. In census years ending in ''2'' and ''7'', we mail and collect the ASM as part of the Economic Census covering the Manufacturing Sector. This survey is an integral part of the Government's statistical program. The ASM furnishes up-to-date estimates of employment and payrolls, hours and wages of production workers, value added by manufacture, cost of materials, value of shipments by product class, inventories, and expenditures for both plant and equipment and structures. The survey provides data for most of these items for each of the 473 industries as defined in the North American Industry Classification System (NAICS). It also provides geographic data by state at a more aggregated industry level.

The survey also provides valuable information to private companies, research organizations, and trade associations. Industry makes extensive use of the annual figures on product class shipments at the U.S. level in its market analysis, product planning, and investment planning. The ASM data are used to benchmark and reconcile monthly and quarterly data on manufacturing production and inventories.

### II. Method of Collection

The ASM statistics are based on a survey which includes two components, mail and nonmail. The mail portion of the survey is a probability sample of about 55,000 manufacturing establishments selected from a total of about 225,000 establishments. These 225,000 establishments represent all manufacturing establishments of multiunit companies (companies that operate at more than one physical location) and all single-establishment manufacturing companies that were mailed forms in the 1997 Economic Census.

The nonmail portion of the survey is defined as all single-establishment manufacturing companies that we tabulated as administrative records in the 1997 Economic Census. Although this portion includes approximately 155,000 establishments, it accounted for less than 2 percent of the estimate for total value of shipments at the total manufacturing level for 1997. No data are collected from this portion of the population, instead data are estimated based on selected information obtained annually from the administrative records of the Internal Revenue Service (IRS) and the Social Security Administrative (SSA). This administrative information, which includes payroll, total employment, industry classification, and physical location, is obtained under conditions which safeguard the confidentiality of both tax and census records.

### III. Data

*MB Number:* 0607–0449.

*Form Number:* MA–10000(L), MA–10000(S).

*Type of Review:* Regular review.

*Affected Public:* Businesses or other for profit, non-profit Institutions, small businesses or organizations, and State or Local Governments.

*Estimated Number of Respondents:* 55,000.

*Estimated Time Per Response:* 3.4 hours.

*Estimated Total Annual Burden Hours:* 187,000.

*Estimated Total Annual Cost:* The estimated cost to the respondents is $4,885,410.

*Respondent's Obligation:* Mandatory.

*Legal Authority:* Title 13, United States Code, sections 182, 224, and 225.

**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 of information; (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 this information collection; they also will become a matter of public record.

Dated: March 7, 2003.

**Madeleine Clayton,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 03–5965 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–07–P

## DEPARTMENT OF COMMERCE

## Foreign-Trade Zones Board

**[Docket 11–2003]**

## Foreign-Trade Zone 75—Phoenix, AZ; Application for Subzone, American Italian Pasta Company, Distribution of Dry Pasta Products, Tolleson, AZ

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Phoenix, Arizona, grantee of FTZ 75, requesting special-purpose subzone status for the dry pasta products warehousing/distribution facility of the American Italian Pasta Company (AIPC), in Tolleson, Arizona. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on March 4, 2003.

The AIPC facility (288,000 sq. ft./1 bldg. on 22.7 acres) is located at 495 South 99th Avenue, Tolleson (Maricopa County), Arizona. It was expanded in 2002 and is expected to become fully operational during the first quarter of 2003. The facility (54 employees initially, with plans to increase to some 200) is used for warehousing, inspection, packaging and distribution of dry pasta products received by all AIPC facilities located in the U.S. and Italy. About 1 percent of production is currently exported. The plant will also be used to manufacture dry pasta for U.S. and export markets, but manufacturing authority is not being requested at this time. Certain dry pasta imports from Italy are subject to anti-dumping/countervailing (AD/CVD) duties.

Zone procedures would exempt AIPC from Customs duty payments (including AD/CVD) on foreign products that are reexported. On domestic sales, the company would be able to defer payments until merchandise is shipped from the plant. FTZ status may also make a site eligible for benefits provided under state/local programs. The application indicates that the savings from zone procedures will help improve the plant's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the following addresses:

1. *Submissions Via Express/Package Delivery Services:* Foreign-Trade-Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099 14th St., NW., Washington, DC 20005; or

2. *Submissions Via the U.S. Postal Service:* Foreign-Trade-Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Ave., NW., Washington, DC 20230.

The closing period for their receipt is May 12, 2003. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to May 27, 2003).

A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade-Zones Board's Executive Secretary at address Number 1 listed above, and at the U.S. Department of Commerce Export Assistance Center, 2901 N. Central Ave., Suite 970, Phoenix, AZ 85012.

Dated: March 4, 2003.

**Dennis Puccinelli,**

*Executive Secretary.*

[FR Doc. 03–6087 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

## Foreign-Trade Zones Board

**[Docket 13–2003]**

## Foreign-Trade Zone 151—Findlay, OH; Application for Extension of Zone Status

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board), by the Findlay Hancock Chamber of Commerce (FHCOC), grantee of Foreign-Trade Zone 151, requesting extension of authority for FTZ 151–Site 2 within the Toledo Customs port of entry. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on March 5, 2003.

FTZ 151–Site 2 was approved on February 10, 1999 (Board Order 1023, 64 FR 8542, 2/22/99). The authorization was for a four-year period ending June 30, 2003, subject to extension upon review. The grantee now requests an indefinite extension of authority for FTZ 151–Site 2. (A temporary time extension (to 6/30/04) was approved until a full Board review of the indefinite extension proposal can be completed (A(27f)–5–03, 3/4/03)).

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at one of the addresses below:

1. *Submissions via Express/Package Delivery Services:* Foreign-Trade Zones Board, U.S. Department of Commerce, Franklin Court Building—Suite 4100W, 1099 14th Street NW., Washington, DC 20005; or

2. *Submissions via the U.S. Postal Service:* Foreign-Trade Zones Board, U.S. Department of Commerce, FCB—Suite 4100W, 1401 Constitution Avenue NW., Washington, DC 20230.

The closing period for their receipt is May 12, 2003. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to May 27, 2003).

A copy of the application and accompanying exhibits will be available for public inspection at the Office of the Foreign-Trade Zones Board's Executive Secretary at the first address listed above, and at the Office of the Findlay/

Hancock County Chamber of Commerce, 123 E. Main Cross Street, Findlay, Ohio 45840.

Dated: March 5, 2003.

**Dennis Puccinelli,**

*Executive Secretary.*

[FR Doc. 03–6086 Filed 3–12–03; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

## International Trade Administration

**[A–570–853]**

## Notice of Amended Final Results of Antidumping Duty Administrative Review: Bulk Aspirin from the People's Republic of China

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of amended final results of antidumping duty administrative review.

**EFFECTIVE DATE:** March 13, 2003.

**FOR FURTHER INFORMATION CONTACT:** Julie Santoboni or Cole Kyle, Office 1, AD/CVD Enforcement, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC 20230; telephone (202) 482–4194 or (202) 482–1503, respectively.

### Scope of Review

The product covered by this review is bulk acetylsalicylic acid, commonly referred to as bulk aspirin, whether or not in pharmaceutical or compound form, not put up in dosage form (tablet, capsule, powders or similar form for direct human consumption). Bulk aspirin may be imported in two forms, as pure ortho-acetylsalicylic acid or as mixed ortho-acetylsalicylic acid. Pure ortho-acetylsalicylic acid can be either in crystal form or granulated into a fine powder (pharmaceutical form). This product has the chemical formula $C_9H_8O_4$. It is defined by the official monograph of the United States Pharmacopoeia (''USP'') 23. It is classified under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheading 2918.22.1000.

Mixed ortho-acetylsalicylic acid consists of ortho-acetylsalicylic acid combined with other inactive substances such as starch, lactose, cellulose, or coloring materials and/or other active substances. The presence of other active substances must be in concentrations less than that specified for particular nonprescription drug combinations of bulk aspirin and active substances as published in the *Handbook of Nonprescription Drugs,* eighth edition, American Pharmaceutical Association. This product is classified under HTSUS subheading 3003.90.0000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

### Amended Final Results

On February 4, 2003, the Department of Commerce (''the Department'') determined that bulk aspirin from the People's Republic of China (''PRC'') is not being sold in the United States at less than normal value, as provided in section 751(a) of the Tariff Act of 1930, as amended (''the Act''). *See Bulk Aspirin from the People's Republic of China; Final Results of Antidumping Duty Administrative Review* (''*Final Results*''), 68 FR 6710 (February 10, 2003). On February 7 and 10, 2003, Shandong Xinhua Pharmaceutical Co., Ltd. (''Shandong'') and Rhodia, Inc. (''petitioner''), respectively, filed timely ministerial error allegations pursuant to 19 CFR 351.224(c)(2). On February 12, 2003 the petitioner filed a reply to Shandong's allegation and on February 18, 2003, Shandong filed a response to the petitioner's February 12, 2003 submission. The other respondent in this review, Jilin Henghe Pharmaceutical Company Ltd. (''Jilin''), did not file a ministerial error allegation.

The petitioner contends that the Department incorrectly rounded one of the surrogate values for caustic soda, incorrectly deducted taxes from the domestic price of acetic acid sold on the Mumbai Dyes Market and assigned the incorrect surrogate labor value for packing labor in Jilin's normal value calculations. The petitioner also alleges that the Department overstated the excise and sales taxes for all domestic values because the deduction of taxes from the *International Chemical Weekly* (''*ICW*'') domestic prices was based on the gross price, when instead it should have been based on the before-tax price. Furthermore the petitioner asserts that the Department did not calculate a portion of the normal value build up associated with one of the inputs. Neither Shandong nor Jilin responded to petitioner's comments.

Shandong contends that the Department incorrectly used a single surrogate value for virgin acetic acid to value all the acetic acid inputs in its calculation of the cost of acetic anhydride production, when instead it should have valued the virgin and recovered acetic acid separately. The petitioner contends that the Department correctly applied the surrogate value of virgin acetic acid to the full quantity of acetic acid used in the production process and that Shandong ignores the distinction between ''recovered'' acetic acid and ''recycled'' or ''reused'' acetic acid. In its response to the petitioner's comments, Shandong argues that recovered, recycled and reused acetic acid are identical and should have the same value.

In accordance with section 735(e) of the Act, we have determined that certain ministerial errors were made in our final results margin calculations. Specifically we find that the incorrect calculation of certain taxes from the *ICW* domestic prices and the incorrect surrogate value of Jilin's packing labor constitute clerical errors. For a detailed discussion of all of the ministerial error allegations and the Department's analysis, see Memorandum to Susan Kuhbach, ''Antidumping Duty Administrative Review of Bulk Aspirin from the People's Republic of China; Allegations of Ministerial Errors' dated March 5, 2003, which is on file in the Central Records Unit, room B–099 of the main Department building.

In accordance with 19 CFR 351.224(e), we are amending the final results of the antidumping duty administrative review of bulk aspirin from the PRC to correct these ministerial errors. However, the amended weighted-average margins are identical to the weighted-average margins in the final results (*see Final Results*). The weighted-average dumping margins for Jilin and Shandong are listed below:

| Producer/manfacturer/exporter | Original weighted-average margin percentage | Amended results weighted-average margin percentage |
|---|---|---|
| Jilin Henghe Pharmaceutical Company Ltd. | 0.04 (*de minimis*) | 0.04 (*de minimis*) |
| Shandong Xinhua Pharmaceutical Co., Ltd. | 0.00 | 0.00 |

**Cash Deposit Rates**

The following antidumping duty deposits will be required on all shipments of bulk aspirin from the PRC entered, or withdrawn from warehouse, for consumption, effective on or after the publication date of the amended final results of this administrative review, as provided by section 751(a)(1) of the Act: (1) For Shandong and Jilin, no antidumping duty deposit will be required; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in the original less-than-fair-value investigation or a previous review, the cash deposit will continue to be the most recent rate published in the final determination or final results for which the manufacturer or exporter received an individual rate; (3) if the exporter is not a firm covered in this review, the previous review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this or any previous reviews, the cash deposit rate will be 144.02 percent, the ''all others'' rate established in the less-than-fair-value investigation.

These cash deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

**Assessment Rates**

Absent an injunction from the U.S. Court of International Trade, the Department will issue appropriate assessment instructions directly to the Customs Service within 15 days of publication of these amended final results of review.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 771(i)(1) of the Act.

Dated: March 6, 2003.

**Joseph A. Spetrini,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 03–6088 Filed 3–12–03; 8:45 am]

**BILLING CODE 3510–DS–P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–821–817]**

### Notice of Amended Final Determination of Sales at Less Than Fair Value: Silicon Metal From the Russian Federation

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Notice of amended final determination in the less-than-fair-value investigation of silicon metal from the Russian Federation.

**EFFECTIVE DATE:** March 13, 2003.

**FOR FURTHER INFORMATION CONTACT:** Cheryl Werner, AD/CVD Enforcement Group III, Office IX, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2667.

**Scope of Investigation**

For purposes of this investigation, the product covered is silicon metal, which generally contains at least 96.00 percent but less than 99.99 percent silicon by weight. The merchandise covered by this investigation also includes silicon metal from Russia containing between 89.00 and 96.00 percent silicon by weight, but containing more aluminum than the silicon metal which contains at least 96.00 percent but less than 99.99 percent silicon by weight. Silicon metal currently is classifiable under subheadings 2804.69.10 and 2804.69.50 of the Harmonized Tariff Schedule of the United States (''HTSUS''). This investigation covers all silicon metal meeting the above specification, regardless of tariff classification.

**Amendment of Final Results**

On February 11, 2003, the Department of Commerce (''the Department'') published a notice of final determination of sales at less than fair value in the investigation of silicon metal from the Russian Federation (''Russia''). *Notice of Final Determination of Sales at Less Than Fair Value: Silicon Metal From the Russian Federation,* 68 FR 6885 (February 11, 2003) (''*Final Determination*'').

Also on February 11, 2003, petitioners timely filed an allegation that the Department made ministerial errors in the *Final Determination,* pursuant to 19 CFR 351.224(c). Bratsk Aluminum Smelter (''BAS'') and (''RTL'') submitted timely rebuttal comments on February 19, 2003, in reply to the petitioners' ministerial error allegations. BAS and RTL did not submit any ministerial error allegations. ZAO Kremny (''Kremny'')/Sual-Kremny-Ural Ltd. (''SKU'') and Pultwen, the other respondent covered by the investigation, did not submit any ministerial error allegations or rebuttal comments in reply to petitioners' ministerial error allegations.

**Silicon Metal Fines**

Petitioners contend that in its *Final Determination,* the Department used overstated production quantities of silicon metal in calculating factor usage rates. Petitioners argue that while the Department included fines in the total production quantities of silicon metal on the basis that silicon metal fines produced by BAS and Kremny/SKU (collectively ''respondents'') were similar in size, chemical composition, and price to commercial grade silicon metal, and the Department also concluded that the quantities of fines used in the calculation represented only sales of fines. Petitioners contend that the production quantities of fines reported by respondents and used by the Department included fines that were recycled and consumed in the production of silicon metal in addition of the fines that were sold. Petitioners claim this overstated the total production quantities used to calculate respondents' factor usage rates, and therefore, resulted in understated factor usage rates.

Petitioners contend that the record shows that both respondents consumed recycled silicon metal fines in the production of silicon metal during the POI. Petitioners explain that the production quantities of fines reported by respondents are larger than the total quantities of fines sold by respondents during the POI. According to petitioners, Kremny/SKU and Pultwen's August 13, 2002, response shows that they reported a quantity of fines recycled during the POI, which were then included in their production quantity. *See* Kremny/SKU and Pultwen's August 13, 2002, response, at 13. Petitioners also contend that the Department verified that only a portion of BAS's total fine production quantity was sold. *See BAS Verification Report,* at Exhibit 5.

Thus, petitioners argue the Department intended to include only the quantity of silicon metal fines sold by respondents in the total production quantity but erroneously included recycled fines as well. Petitioners explain that to correct this error, the Department should (1) subtract the

quantities of fines that were recycled and consumed in the production from the total quantities of fines included in the total production quantities and (2) recalculate respondents' factor usage rates using the reduced production quantities. Petitioners explain that the volume of fines recycled by BAS during the POI is not in the record of this investigation, and therefore, as facts available, the Department should subtract the volume of fines sold that was verified from the total quantity of fines produced during the POI. Alternatively, petitioners also suggest that the Department could estimate the volume of fines recycled by BAS using the percentage amount of fines recycled by Kremny in relation to its total output.

BAS and RTL contend that the Department determined in its *Final Determination* that 0–5 mm silicon metal, or fines, should be included in the production quantity because ''excluding fines from the production quantity used to calculate the reported factors would overstate the factors of production.'' *See Issues and Decision Memorandum,* at Comment 11. BAS and RTL argue that the Department noted: That fines were within the scope of this investigation; that it verified that BAS made sales of fines; and that these sales were not made at a very substantial discount compared to normal-sized silicon metal. *See id.* Thus, BAS and RTL argue that the Department determined that fines produced by BAS were commercial-grade silicon metal. Accordingly, BAS and RTL explain that pursuant to *Silicon Metal from Brazil,* the Department properly determined that production costs should be allocated to fines produced by BAS.

BAS and RTL also contend that recycled fines were not included in the reported production quantities for BAS, which is demonstrated by the record. BAS and RTL explain that production documents show a small amount of material added to prevent the molten metal from sticking to the slab, but this amount was not included in BAS's reported total production quantity.

**Department's Position**

We disagree with petitioners.

Petitioners' request that the Department exclude recycled fines from the production quantity is not ministerial in nature, but rather involves a methodological change. This is because if the Department were to remove recycled fines from the total production quantity of silicon metal, we would not be allocating any costs to their production. Therefore, we would, in effect, be treating recycled fines as byproducts because the Department does not allocate costs to byproducts. This would be contrary to the Department's decision in the *Final Determination. See Issues and Decision Memorandum,* at Comment 11. A ministerial error is defined under 19 CFR 351.224(f) as ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial.'' Petitioners' request, however, would require the Department to revisit its entire methodology for recognizing fines. Accordingly, we have not made the requested change, because it is not ''ministerial'' in nature.

**Indirect Labor**

Petitioners contend that the Department did not include indirect labor in the calculation of normal value for BAS in its *Final Determination.* Petitioners argue that the Department indicated that it intended to include both direct labor and indirect labor in the calculation of normal value for BAS, according to the *BAS and RTL Final Analysis Memorandum. See Analysis Memorandum of Bratsk Aluminum Smelter and Rual Trade Limited: Final Determination in the Less Than Fair Value Investigation of Silicon Metal from the Russian Federation,* at page 5 (February 3, 2003) (''*BAS and RTL Final Analysis Memo*'') (under the Normal Value calculation heading: ''TOT_LABOR = DIRLAB_F + INDLAB_F''). Petitioners explain that it is necessary to include indirect labor in the calculation of normal value because the surrogate-valued amount for factory overhead used by the Department does not include any amount for indirect labor. Petitioners explain that the computer program used by the Department to calculate the final margin for BAS does not include indirect labor in the calculation of normal value. Petitioners contend that the Department should include indirect labor in the calculation of normal value for BAS.

BAS and RTL contend that petitioners have identified a methodological issue regarding how to account for labor costs not directly related to production of subject merchandise under a non-market economy methodology, rather than an arithmetic or duplication error that is appropriate to address as a ministerial error. BAS and RTL explain that BAS reported, as indirect labor, the per-unit hours of personnel involved in the maintenance and servicing (*e.g.,* cleaning, catering) of the production facilities, and involved in the handling of transportation of raw materials and finished goods. BAS and RTL note that BAS included an allocated amount for the hours of executives, managers, and specialists who are involved indirectly in the production of silicon metal, in its reported direct labor. BAS and RTL contend that the labor cost of such personnel is normally classified as factory overhead or selling, general and administrative expenses under standard accounting principles. Accordingly, because the Department values factory overhead and general and administrative expenses using the financial statements of a surrogate company, under the non-market economy methodology, it is not necessary to include an amount for indirect labor in the Department's margin calculation, because this would double-count these labor expenses. Therefore, because BAS's reported direct labor already includes allocated amounts for indirect labor, and because indirect labor is also included in the surrogate financial information used in the margin calculation, the Department should not include additional labor hours in its margin calculation.

**Department's Position**

We agree with petitioners. We inadvertently excluded indirect labor in the calculation of normal value for BAS in the *Final Determination.* As BAS explained above, its reported indirect labor consists of the per-unit hours of personnel involved in the maintenance and servicing (*e.g.,* cleaning, catering) of the production facilities, and involved in the handling of transportation of raw materials and finished goods, and is properly classified as indirect labor. Therefore, we revised our Final Determination, to include BAS's reported indirect labor in BAS's margin program calculation.

**Wood Charcoal Freight Cost**

Petitioners argue that the Department incorrectly calculated the wood charcoal freight cost for BAS in its *Final Determination.* Petitioners argue that the Department calculated the wrong weighted-average distance between BAS and wood charcoal suppliers. Petitioners contend that the Department should correct its wood charcoal freight cost calculation.

BAS and RTL agree with petitioners that the Department miscalculated the weighted-average distance of BAS's wood charcoal suppliers. However, BAS and RTL disagree with petitioners' calculation of the per-unit freight cost for wood charcoal, and propose their own calculation of the per-unit freight cost for wood charcoal.

**Department's Position**

We agree with petitioners and BAS and RTL, that we incorrectly calculated the weighted-average distance between BAS and wood charcoal suppliers. In the *Final Determination,* we inadvertently excluded certain suppliers of wood charcoal for BAS. We revised our *Final Determination,* to include the correct per-unit freight cost for wood charcoal in BAS's margin program calculation.

Therefore, we are amending the *Final Determination* to reflect the correction of the above-cited ministerial errors. All changes made to the margin program can be found in the analysis memorandum. *See Memorandum to the File from Cheryl Werner, Case Analyst to James C. Doyle, Program Manager, Final Analysis for BAS for the Amended Final Determination of the Antidumping Duty Investigation of Silicon Metal from the Russian Federation,* dated March 6, 2003.

The weighted-average dumping margins are as follows:

| Producer/manufacturer exporter | Final weighted-average margin (percent) | Amended final weighted average margin (percent) |
|---|---|---|
| Bratsk Aluminum Smelter | 77.51 | 79.42 |
| ZAO Kremny/Sual-Kremny-Ural Ltd | 54.79 | 56.11 |

Consequently, we are issuing and publishing this amended final determination and notice in accordance with section 751(a)(1) of the Act.

Dated: March 6, 2003.

**Joseph A. Spetrini,**

*Acting Assistant Secretary for Import Administration.*

[FR Doc. 03–6089 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

**[A–580–834]**

### Stainless Steel Sheet and Strip in Coils From The Republic of Korea: Notice of Amended Final Results of Antidumping Duty Administrative Review

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**ACTION:** Amended final results of antidumping duty administrative review of stainless steel sheet and strip in coils from the Republic of Korea.

**EFFECTIVE DATE:** March 13, 2003.

**FOR FURTHER INFORMATION CONTACT:** Laurel LaCivita or Robert Bolling, Enforcement Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230; telephone: (202)482–4243, or (202)482–3434, respectively.

**Amendment of Final Results**

On February 10, 2003, the U.S. Department of Commerce (''Department'') published in the **Federal Register** the results of its administrative review of the antidumping duty order on stainless steel sheet and strip in coils (''SSSS'') from the Republic of Korea covering the period July 1, 2000, through June 30, 2001. *See Stainless Steel Sheet and Strip in Coils From the Republic of Korea; Final Results and Partial Rescission of Antidumping Duty Administrative Review, 68 FR 6713 (February 10, 2003) (''Final Results'').*

On February 10, 2003, respondent Pohang Iron & Steel Co., Ltd. (''POSCO'') filed a ministerial error allegation pursuant to section 351.224(c)(2) of the Department's regulations. Petitioners did not comment on any ministerial errors concerning the final results of this review. As a result of our analysis of POSCO's allegations, we are amending the Final Results in the antidumping review of SSSS from the Republic of Korea.

**Scope of the Review**

For purposes of this administrative review, the products covered are certain stainless steel sheet and strip in coils. Stainless steel is an alloy steel containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. The subject sheet and strip is a flat-rolled product in coils that is greater than 9.5 mm in width and less than 4.75 mm in thickness, and that is annealed or otherwise heat treated and pickled or otherwise descaled. The subject sheet and strip may also be further processed (*e.g.*, cold-rolled, polished, aluminized, coated, *etc.*) provided that it maintains the specific dimensions of sheet and strip following such processing.

The merchandise subject to this review is classified in the Harmonized Tariff Schedule of the United States (HTS) at subheadings: 7219.13.0031, 7219.13.0051, 7219.13.0071, 7219.1300.81,[1] 7219.14.0030, 7219.14.0065, 7219.14.0090, 7219.32.0005, 7219.32.0020, 7219.32.0025, 7219.32.0035, 7219.32.0036, 7219.32.0038, 7219.32.0042, 7219.32.0044, 7219.33.0005, 7219.33.0020, 7219.33.0025, 7219.33.0035, 7219.33.0036, 7219.33.0038, 7219.33.0042, 7219.33.0044, 7219.34.0005, 7219.34.0020, 7219.34.0025, 7219.34.0030, 7219.34.0035, 7219.35.0005, 7219.35.0015, 7219.35.0030, 7219.35.0035, 7219.90.0010, 7219.90.0020, 7219.90.0025, 7219.90.0060, 7219.90.0080, 7220.12.1000, 7220.12.5000, 7220.20.1010, 7220.20.1015, 7220.20.1060, 7220.20.1080, 7220.20.6005, 7220.20.6010, 7220.20.6015, 7220.20.6060, 7220.20.6080, 7220.20.7005, 7220.20.7010, 7220.20.7015, 7220.20.7060, 7220.20.7080, 7220.20.8000, 7220.20.9030, 7220.20.9060, 7220.90.0010, 7220.90.0015, 7220.90.0060, and 7220.90.0080. Although the HTS subheadings are provided for convenience and Customs purposes, the Department's written description of the merchandise under review is dispositive.

Excluded from the scope of this review are the following: (1) Sheet and strip that is not annealed or otherwise heat treated and pickled or otherwise descaled, (2) sheet and strip that is cut to length, (3) plate (*i.e.*, flat-rolled stainless steel products of a thickness of 4.75 mm or more), (4) flat wire (*i.e.*, cold-rolled sections, with a prepared edge, rectangular in shape, of a width of not more than 9.5 mm), and (5) razor

[1] Due to changes to the HTS numbers in 2001, 7219.13.0030, 7219.13.050, 7219.13.0070, and 7219.13.0080 are now 7219. 13.0031, 7219.13.0051,7219.13.0071, and 7219.13.0081, respectively.

blade steel. Razor blade steel is a flat-rolled product of stainless steel, not further worked than cold-rolled (cold-reduced), in coils, of a width of not more than 23 mm and a thickness of 0.266 mm or less, containing, by weight, 12.5 to 14.5 percent chromium, and certified at the time of entry to be used in the manufacture of razor blades. *See* chapter 72 of the HTS, ''Additional U.S. Note'' 1(d).

In response to comments by interested parties, the Department has determined that certain specialty stainless steel products are also excluded from the scope of this review. These excluded products are described below.

Flapper valve steel is defined as stainless steel strip in coils containing, by weight, between 0.37 and 0.43 percent carbon, between 1.15 and 1.35 percent molybdenum, and between 0.20 and 0.80 percent manganese. This steel also contains, by weight, phosphorus of 0.025 percent or less, silicon of between 0.20 and 0.50 percent, and sulfur of 0.020 percent or less. The product is manufactured by means of vacuum arc remelting, with inclusion controls for sulphide of no more than 0.04 percent and for oxide of no more than 0.05 percent. Flapper valve steel has a tensile strength of between 210 and 300 ksi, yield strength of between 170 and 270 ksi, plus or minus 8 ksi, and a hardness (Hv) of between 460 and 590. Flapper valve steel is most commonly used to produce specialty flapper valves in compressors.

Also excluded is a product referred to as suspension foil, a specialty steel product used in the manufacture of suspension assemblies for computer disk drives. Suspension foil is described as 302/304 grade or 202 grade stainless steel of a thickness between 14 and 127 microns, with a thickness tolerance of plus-or-minus 2.01 microns, and surface glossiness of 200 to 700 percent Gs. Suspension foil must be supplied in coil widths of not more than 407 mm, and with a mass of 225 kg or less. Roll marks may only be visible on one side, with no scratches of measurable depth. The material must exhibit residual stresses of 2 mm maximum deflection, and flatness of 1.6 mm over 685 mm length.

Certain stainless steel foil for automotive catalytic converters is also excluded from the scope of this review. This stainless steel strip in coils is a specialty foil with a thickness of between 20 and 110 microns used to produce a metallic substrate with a honeycomb structure for use in automotive catalytic converters. The steel contains, by weight, carbon of no more than 0.030 percent, silicon of no more than 1.0 percent, manganese of no more than 1.0 percent, chromium of between 19 and 22 percent, aluminum of no less than 5.0 percent, phosphorus of no more than 0.045 percent, sulfur of no more than 0.03 percent, lanthanum of less than 0.002 or greater than 0.05 percent, and total rare earth elements of more than 0.06 percent, with the balance iron.

Permanent magnet iron-chromium-cobalt alloy stainless strip is also excluded from the scope of this review. This ductile stainless steel strip contains, by weight, 26 to 30 percent chromium, and 7 to 10 percent cobalt, with the remainder of iron, in widths 228.6 mm or less, and a thickness between 0.127 and 1.270 mm. It exhibits magnetic remanence between 9,000 and 12,000 gauss, and a coercivity of between 50 and 300 oersteds. This product is most commonly used in electronic sensors and is currently available under proprietary trade names such as ''Arnokrome III.'' [2]

Certain electrical resistance alloy steel is also excluded from the scope of this review. This product is defined as a non-magnetic stainless steel manufactured to American Society of Testing and Materials (''ASTM'') specification B344 and containing, by weight, 36 percent nickel, 18 percent chromium, and 46 percent iron, and is most notable for its resistance to high temperature corrosion. It has a melting point of 1390 degrees Celsius and displays a creep rupture limit of 4 kilograms per square millimeter at 1000 degrees Celsius. This steel is most commonly used in the production of heating ribbons for circuit breakers and industrial furnaces, and in rheostats for railway locomotives. The product is currently available under proprietary trade names such as ''Gilphy 36.'' [3]

Certain martensitic precipitation-hardenable stainless steel is also excluded from the scope of this review. This high-strength, ductile stainless steel product is designated under the Unified Numbering System (''UNS'') as S45500-grade steel, and contains, by weight, 11 to 13 percent chromium, and 7 to 10 percent nickel. Carbon, manganese, silicon and molybdenum each comprise, by weight, 0.05 percent or less, with phosphorus and sulfur each comprising, by weight, 0.03 percent or less. This steel has copper, niobium, and titanium added to achieve aging, and will exhibit yield strengths as high as 1700 Mpa and ultimate tensile strengths as high as 1750 Mpa after aging, with elongation percentages of 3 percent or less in 50 mm. It is generally provided in thicknesses between 0.635 and 0.787 mm, and in widths of 25.4 mm. This product is most commonly used in the manufacture of television tubes and is currently available under proprietary trade names such as ''Durphynox 17.'' [4]

Finally, three specialty stainless steels typically used in certain industrial blades and surgical and medical instruments are also excluded from the scope of this review. These include stainless steel strip in coils used in the production of textile cutting tools (*e.g.*, carpet knives).[5] This steel is similar to AISI grade 420 but containing, by weight, 0.5 to 0.7 percent of molybdenum. The steel also contains, by weight, carbon of between 1.0 and 1.1 percent, sulfur of 0.020 percent or less, and includes between 0.20 and 0.30 percent copper and between 0.20 and 0.50 percent cobalt. This steel is sold under proprietary names such as ''GIN4 Mo.'' The second excluded stainless steel strip in coils is similar to AISI 420–J2 and contains, by weight, carbon of between 0.62 and 0.70 percent, silicon of between 0.20 and 0.50 percent, manganese of between 0.45 and 0.80 percent, phosphorus of no more than 0.025 percent and sulfur of no more than 0.020 percent. This steel has a carbide density on average of 100 carbide particles per 100 square microns. An example of this product is ''GIN5'' steel. The third specialty steel has a chemical composition similar to AISI 420 F, with carbon of between 0.37 and 0.43 percent, molybdenum of between 1.15 and 1.35 percent, but lower manganese of between 0.20 and 0.80 percent, phosphorus of no more than 0.025 percent, silicon of between 0.20 and 0.50 percent, and sulfur of no more than 0.020 percent. This product is supplied with a hardness of more than Hv 500 guaranteed after customer processing, and is supplied as, for example, ''GIN6''.[6]

**Ministerial Error**

A ministerial error is defined in section 351.224(f) of our regulations as ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial.'' Section 351.224(e) of our regulations provides that we ''will

[2] ''Arnikrome III'' is a trademark of the Arnold Engineering Company.

[3] ''Gilphy 36'' is a trademark of Imply, S.A

[4] ''Durphnox 17'' is a trademark of Imphy, S.A.

[5] This list of uses is illustrative and provided for descriptive purposes only.

[6] ''GIN4 Mo,'' ''GIN5'' and ''GIN6'' are the proprietary grades of Hitachi Metals America, Ltd.

analyze any comments received and, if appropriate * * * correct any ministerial error by amending * * * the final results of review. * * *'' After reviewing POSCO's allegations, we have determined in accordance with section 351.224 of the Department's regulations, that the final results of review include the ministerial error discussed below.

*Comment 1: L-Grade Adjustment for Models Sold Exclusively in the United States*

POSCO contends that the Department made an error in merging the cost of production (''COP'') and constructive value (''CV'') files that failed to implement its stated decision in the final results of review to apply the minor corrections to the L-grade adjustment reported at verification to those models sold exclusively in the United States. As a result, POSCO claims that certain models sold exclusively in the U.S. market did not have variable or total cost of manufacturing (''VCOM'' or ''TCOM'') applied to them during the model match sequence of the computer program. Consequently, these models did not find an appropriate match in the home market and were compared to CV in error for the final results of review.

To correct this error, POSCO proposed a number of programming changes: (1) Insert language creating a duplicate cost file for the U.S. sales; (2) create the VCOM and TCOM information for the U.S. sales before merging the cost files with the home market sales files; and, (3) delete the calculation of VCOM and TCOM after the merge of the COP and home market sales databases. *See* POSCO's February 10, 2003 ministerial error allegation letter.

*Department's Position*

We agree with POSCO that the program used in the final results of review failed to correctly apply the L-grade adjustment to the models sold exclusively in the United States, and therefore, to determine the appropriate model matches for the final results of review. However, our analysis reveals that POSCO erroneously equated the total cost of production in the United States (''TCOMU'') with the total cost of manufacturing rather than the total cost of production, thereby omitting selling, general and administrative expenses (SG&A) from the calculation of TCOMU. Therefore, we have revised our calculations to appropriately merge the COP and CV files, and to correctly calculate TCOMU. *See Analysis memorandum for the amended final results of review for stainless steel sheet and strip in coils from Korea—Pohang Iron and Steel Company (''POSCO'')* dated March 6, 2003.

**Amended Final Results**

We are amending the final results of the administrative review on SSSS from the Republic of Korea covering the period July 1, 2000, through June 30, 2001, pursuant to section 751(h) of the Act. As a result of this redetermination, the recalculated final weighted-average margin for POSCO is as follows:

| Exporter/manufacturer | Weighted average margin in the final (percent) | Revised weighted average margin (percent) |
|---|---|---|
| POSCO | .98 | .92 |

The cash deposit rate for POSCO of 0.92 percent ad valorem is effective on all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice, and will remain in effect until publication of the final results of the next administrative review.

Accordingly, the Department will determine, and the Customs Service will assess, antidumping duties on all entries of subject merchandise from POSCO during the period July 1, 2000, through June 30, 2001, in accordance with this amended final results.

This amended final results and notice are in accordance with sections 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and section 351.221 of the Department's regulations.

Dated: March 4, 2003.

**Faryar Shirzad,**

*Assistant Secretary for Import Administration.*

[FR Doc. 03–6090 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 031003A]**

### Proposed Information Collection; Comment Request; Application for Commercial Fisheries Authorization Under Section 118 of the Marine Mammal Protection Act

**AGENCY:** National Oceanic and Atmospheric Administration (NOAA).

**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:** Written comments must be submitted on or before May 12, 2003.

**ADDRESSES:** Direct all written 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 and instructions should be directed to Patricia Lawson, 301–713–2322, or at *Patricia.Lawson@noaa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Abstract**

The Marine Mammal Protection Act (MMPA) requires any commercial fisher operating in a Category I or II fishery to register for a certificate of authorization that will allow the fisher to take marine mammals incidental to commercial fishing operations. Category I and II fisheries are those identified by NOAA as having either frequent or occasional takings of marine mammals.

**II. Method of Collection**

A paper form is used.

**III. Data**

*OMB Number*: 0648–0293.
*Form Number*: None.
*Type of Review*: Regular submission.
*Affected Public*: Business or other for-profit organizations, individuals or households.

*Estimated Number of Respondents*: 12,000.

*Estimated Time Per Response*: 15 minutes for a new application, and 9 minutes for a renewal application.

*Estimated Total Annual Burden Hours*: 2,800.

*Estimated Total Annual Cost to Public*: $304,440.

## 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 of information; (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 this information collection; they also will become a matter of public record.

Dated: March 7, 2003.

**Gwellnar Banks,**

*Management Analyst, Office of the Chief Information Officer.*

[FR Doc. 03–6106 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–22–S

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## DEPARTMENT OF COMMERCE

## National Oceanic and Atmospheric Administration

**[I.D. 022103F]**

## Marine Mammals; File No. 876–1402

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

**ACTION:** Issuance of permit amendment.

**SUMMARY:** Notice is hereby given that Howard C. Rosenbaum, Ph.D. and Robert DeSalle, Ph.D., American Museum of Natural History, Molecular Systematics Laboratory, 79th St. & Central Park West, New York, New York 10024, has been issued an amendment to scientific research Permit No. 876–1402–00 to extend the expiration date through June 30, 2003.

**ADDRESSES:** The amendment and related documents are available for review upon written request or by appointment in the following office(s):Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301)713–2289; fax (301)713–0376; andNortheast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298; phone (978)281–9200; fax (978)281–9371.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Skidmore or Ruth Johnson, (301)713–2289.

**SUPPLEMENTARY INFORMATION:** The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the provisions of 50 CFR 216.39 of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the provisions of the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Issuance of this amendment, as required by the ESA was based on a finding that such permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which is the subject of this permit; and (3) is consistent with the purposes and policies set forth in section 2 of the ESA.

Dated: March 7, 2003.

**Stephen L. Leathery,**

*Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 03–6105 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–22–S

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## DEPARTMENT OF COMMERCE

## Patent and Trademark Office

## Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) has submitted 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:* United States Patent and Trademark Office (USPTO).

*Title:* Customer Input—Patent and Trademark Customer Surveys.

*Form Number(s):* Form numbers will be determined as applicable for the various surveys.

*Agency Approval Number:* 0651–0038.

*Type of Request:* Reinstatement, with change, of a previously approved collection for which approval has expired.

*Burden:* 3,100 hours annually.

*Number of Respondents:* 8,100 responses per year.

*Avg. Hours Per Response:* Based on results from testing the various types of surveys with the representative customer groups and with internal test groups, the USPTO estimates that it takes the public 15 minutes to complete telephone surveys and face-to-face interviews, 5 minutes to complete questionnaires, customer surveys (both paper and electronic), and comment cards, and 2 hours to participate in focus groups. The USPTO estimates that it takes the public 30 minutes to complete the paper version of the annual patent and annual trademark customer satisfaction surveys, but only 20 minutes to complete the same survey electronically.

*Needs and Uses:* The public uses the various types of surveys to express their opinions about the services and information products offered by the USPTO and about the quality of the customer service that they receive from the USPTO. Additionally, these various surveys allow the public to offer their suggestions and comments concerning the USPTO, its services and information products, and its customer service. Depending on the type of survey, the public can provide their comments on the spot to the interviewer, or complete the survey at their own pace and either mail their responses to the USPTO or submit their responses electronically via a web-based survey. The USPTO uses the data collected from these surveys for strategic planning, the allocation of resources, the establishment of performance goals, and the verification and establishment of service standards. The USPTO also uses this data to assess customer satisfaction with USPTO products and services, assess customer priorities in service characteristics, and identify areas where service levels differ from customer expectations.

*Affected Public:* Individuals or households, business or other for-profit, and not-for-profit institutions.

*Frequency:* On occasion.

*Respondent's Obligation:* Voluntary.

*OMB Desk Officer:* David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Susan K. Brown, Records Officer, Office of Data Architecture and Services, Data Administration Division, USPTO, Suite

310, 2231 Crystal Drive, Washington, DC 20231, by telephone at 703–308–7400, or by e-mail at *susan.brown@uspto.gov.*

Written comments and recommendations for the proposed information collection should be sent on or before April 14, 2003 to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: March 6, 2003.

**Susan K. Brown,**

*Records Officer, USPTO, Office of Data Architecture and Services, Data Administration Division.*

[FR Doc. 03–6049 Filed 3–12–03; 8:45 am]

BILLING CODE 3510–16–P

## DEPARTMENT OF EDUCATION

### Notice of Proposed Information Collection Requests

**AGENCY:** Department of Education.

**SUMMARY:** The Leader, Regulatory Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

**DATES:** Interested persons are invited to submit comments on or before May 12, 2003.

**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 Leader, Regulatory Management Group, Office of the Chief Information Officer, 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.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: March 7, 2003.

**John D. Tressler,**

*Leader, Regulatory Management Group, Office of the Chief Information Officer.*

### Federal Student Aid

*Type of Review:* Revision of a currently approved collection.

*Title:* Student Aid Internet Gateway (SAIG) Enrollment Document (JS).

*Frequency:* On occasion.

*Affected Public:* Not-for-profit institutions (primary), Businesses or other for-profit, State, Local, or Tribal Gov't, SEAs or LEAs.

*Reporting and Recordkeeping Hour Burden:*

Responses: 6902.

Burden Hours: 6902.

*Abstract:* Enrollment in SAIG allows eligible entities to exchange Title IV information electronically with the Department of Education. Users are able to receive, transmit, view and update student financial aid data via SAIG. Eligible respondents include postsecondary schools that participate in federal student financial aid programs, financial aid servicers, state and guaranty agencies, lenders, and need analysis servicers.

Written requests for information should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202–4651 or to the e-mail address *Vivian.reese@ed.gov.* Requests may also be faxed to 202–708–9346. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Joseph Schubart at his e-mail address *Joe.Schubart@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. 03–5998 Filed 3–12–03; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF EDUCATION

### Brown v. Board of Education 50th Anniversary Commission; Meeting

**AGENCY:** Brown v. Board of Education 50th Anniversary Commission, U.S. Department of Education (ED).

**ACTION:** Notice of meeting.

**SUMMARY:** This notice provides the schedule of a forthcoming meeting of the Brown v. Board of Education 50th Anniversary Commission. This notice also describes the functions of the commission. This document is intended to notify the general public of their opportunity to attend.

**DATE AND TIME:** March 27, 2003, at 8:45 a.m.

**ADDRESSES:** Harvard University—Harvard Law School—Pound Hall, 1536 Massachusetts Avenue, Cambridge, MA 02138, (617) 495–3100.

**FOR FURTHER INFORMATION CONTACT:** Daniel W. Sutherland, Chief of Staff, 330 C Street SW., Washington, DC 20202, (202) 205–8162.

**SUPPLEMENTARY INFORMATION:** The *Brown* v. *Board of Education* 50th Anniversary Commission is established under Public Law 107–41 to commemorate the 50th anniversary of the Brown decision. The Commission, in conjunction with the U.S. Department of Education, is responsible for planning and coordinating public education activities and initiatives. Also, the Commission, in cooperation with the Brown Foundation for Educational Equity, Excellence, and Research in Topeka, Kansas, and such other public or private entities as the Commission deems appropriate, is responsible for encouraging, planning, developing, and coordinating observances of the anniversary of the Brown decision. The meeting of the Commission is open to the public. Individuals who will need accommodations for a disability in order to attend the meeting (i.e., interpreting services, assistive listening devices, materials in alternative format) should notify Gwendolen Long at (202) 205–9556 by no later than March 21, 2003. We will attempt to meet requests after that date, but cannot guarantee availability.

Dated: March 6, 2003.

**Gerald A. Reynolds,**

*Assistant Secretary for Civil Rights.*

[FR Doc. 03–5999 Filed 3–12–03; 8:45 am]

**BILLING CODE 4000–01–M**

## DEPARTMENT OF ENERGY

### Notice of Intent to Prepare an Environmental Impact Statement for Decommissioning and/or Long-Term Stewardship at the West Valley Demonstration Project and Western New York Nuclear Service Center

**AGENCY:** Department of Energy.

**ACTION:** Notice of Intent.

**SUMMARY:** The U.S. Department of Energy (DOE) and the New York State Energy Research and Development Authority (NYSERDA) are announcing their intent to prepare an Environmental Impact Statement (EIS) for Decommissioning and/or Long-Term Stewardship at the West Valley Demonstration Project (WVDP) and Western New York Nuclear Service Center (also known as the ''Center''). The U.S. Nuclear Regulatory Commission (NRC), the U.S. Environmental Protection Agency (EPA), and the New York State Department of Environmental Conservation (NYSDEC) will participate as cooperating agencies under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*). In addition, NYSDEC will participate as an involved agency under the New York State Environmental Quality Review Act (SEQRA) with respect to NYSERDA's proposed actions. DOE, under NEPA, and NYSERDA, under SEQRA, plan to evaluate the range of reasonable alternatives in this EIS to address their respective responsibilities at the Center, including those under the West Valley Demonstration Project Act (Pub. L. 96–368), Atomic Energy Act of 1954 (as amended), and all other applicable Federal and State statutes.

This EIS will revise the Draft Environmental Impact Statement for Completion of the West Valley Demonstration Project and Closure or Long-Term Management of Facilities at the Western New York Nuclear Service Center (DOE/EIS–0226–D, January 1996, also referred to as the 1996 Cleanup and Closure Draft EIS). Based on decommissioning criteria for the WVDP issued by NRC since the Cleanup and Closure EIS was published, DOE and NYSERDA propose to evaluate five alternatives: Unrestricted Site Release, Partial Site Release without Restrictions, Partial Site Release with Restrictions, Monitor and Maintain under Current Operations, and No-Action.

**DATES:** DOE and NYSERDA are inviting public comments on the scope and content of the Decommissioning and/or Long-Term Stewardship EIS during a public comment period commencing with the date of publication of this Notice and ending on April 28, 2003. DOE and NYSERDA will hold two public scoping meetings on the EIS at the Ashford Office Complex, located at 9030 Route 219 in the Town of Ashford, NY, from 7 to 9:30 p.m. on April 9, 2003 and April 10, 2003.

**ADDRESSES:** Address comments on the scope of the Decommissioning and/or Long-Term Stewardship EIS to the DOE Document Manager: Mr. Daniel W. Sullivan, West Valley Demonstration Project, U.S. Department of Energy, WV–49, 10282 Rock Springs Road, West Valley, New York 14171, Telephone: (800) 633–5280, Facsimile: (716) 942–4199, E-mail: *sonja.allen@wvnsco.com.*

The ''Public Reading Rooms'' section under **SUPPLEMENTARY INFORMATION** lists the addresses of the reading rooms where documents referenced herein are available.

**FOR FURTHER INFORMATION, CONTACT:** For information regarding the WVDP or the EIS, contact Mr. Daniel Sullivan as described above. Those seeking general information on DOE's NEPA process should contact: Ms. Carol M. Borgstrom, (EH–42), Director, Office of NEPA Policy and Compliance, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, *Telephone:* (202) 586–4600, *Facsimile:* (202) 586–7031, or leave a message at 1–800–472–2756, toll-free.

Questions for NYSERDA should be directed to: Mr. Paul J. Bembia, New York State Energy Research and Development Authority, 10282 Rock Springs Road, West Valley, New York 14171, *Telephone:* (716) 942–4900, *Facsimile:* (716) 942–2148, E-mail: *pjb@nyserda.org.*

Those seeking general information on the SEQRA process should contact: Mr. Hal Brodie, Deputy Counsel, New York State Energy Research and Development Authority, 17 Columbia Circle, Albany, New York 12203–6399, *Telephone:* (518) 862–1090, ext. 3280, *Facsimile:* (518) 862–1091, *E-mail: hb1@nyserda.org.*

This Notice of Intent will be available on the internet at *http://tis.eh.doe.gov/nepa,* under ''What's New.'' Additional information about the WVDP is also available on the internet at *http://www.wv.doe.gov/linkingpages/insidewestvalley.htm.*

**SUPPLEMENTARY INFORMATION:** DOE and NYSERDA intend to prepare a revised draft Environmental Impact Statement (EIS) for Decommissioning and/or Long-Term Stewardship at the WVDP and Western New York Nuclear Service Center to examine the potential environmental impacts of the proposed action to decommission and/or maintain long-term stewardship at the Center. The NRC, the EPA, and NYSDEC will participate as cooperating agencies under NEPA. NYSDEC will also participate as an involved agency under SEQRA with respect to NYSERDA's proposed actions. DOE, under NEPA, and NYSERDA, under SEQRA, plan to evaluate the range of reasonable alternatives in this EIS to address their respective responsibilities at the Center, including those under the WVDP Act, Atomic Energy Act of 1954 (as amended), and all other applicable Federal and State statutes.

### Background

The Western New York Nuclear Service Center consists of a 3,345-acre reservation in rural western New York that is the location of the only NRC-licensed commercial spent nuclear fuel reprocessing facility to have ever operated in the United States. Reprocessing operations resulted in the generation of approximately 600,000 gallons of liquid high-level waste (HLW), which was stored in large underground tanks adjacent to the reprocessing facility. NYSERDA holds title to the Center on behalf of the people of the State of New York. (See H. Rep. No. 96–1000 at 4 (1980) reprinted in 1980 U.S.S.C.A.N 3102, 3103.)

The WVDP Act of 1980 required DOE to solidify the HLW, transport it to a Federal geologic repository, dispose of the low-level waste (LLW) and transuranic (TRU) waste generated from Project activities, and decontaminate and decommission the facilities used for the Project. The Act also authorized NRC to prescribe decommissioning criteria for the WVDP. The NRC has placed NYSERDA's NRC site license in abeyance during DOE's fulfillment of its WVDP Act requirements.

Pursuant to the WVDP Act, on October 1, 1980, DOE and NYSERDA entered into a Cooperative Agreement (amended September 19, 1981) that established a framework for the implementation of the Project. Under the agreement, NYSERDA has made available to DOE, without transfer of title, an approximately 200-acre portion of the Center, known as the ''Project Premises,'' which includes a formerly operated spent nuclear fuel reprocessing plant, spent nuclear fuel receiving and

storage area, underground liquid HLW storage tanks, and a liquid LLW treatment facility with associated lagoons, as well as other facilities. Most of the facilities on the Project premises were radioactively contaminated from reprocessing operations and are located on a geographic area of the Center known as the North Plateau. Among the other facilities located within the Project Premises is a radioactive waste disposal area known as the NRC-licensed disposal area (NDA). Adjacent to the Project Premises is a radioactive waste disposal area known as the State Licensed Disposal Area (SDA) for which NYSERDA has operational responsibility. Both the NDA and SDA are located on the South Plateau geographic area of the Center.

In 1987, DOE agreed, in a Stipulation of Compromise settling a lawsuit filed by local citizens, to evaluate the feasibility of onsite disposal of LLW generated as a result of Project activities in a Cleanup and Closure EIS, and to initiate the EIS process by the end of calendar year 1988. DOE and NYSERDA jointly issued the resulting Draft EIS for Completion of the West Valley Demonstration Project and Closure or Long-Term Management of Facilities at the Western New York Nuclear Service Center (DOE/EIS–0226-D, also known as the ''Cleanup and Closure EIS'') in 1996. The Cleanup and Closure draft EIS evaluated a range of alternatives that included a broad scope of waste management and decontamination/decommissioning activities. However, the draft EIS did not identify a preferred alternative.

In 2001, DOE revised its NEPA strategy to continue its EIS process in order to complete its obligations under the WVDP Act. DOE announced that it would prepare a separate EIS to address decontamination and near-term waste management activities for which it is solely responsible under the Act (66 FR 16647, March 26, 2001). In addition, DOE and NYSERDA would jointly prepare a second EIS for decommissioning and/or long-term stewardship to address activities for which each party is responsible. After considering public comments on the March 26, 2001, NOI and new information identified under ''New Information to be Evaluated'' below, DOE believes the scopes of both EISs should be further modified as follows. The first EIS, the West Valley Waste Management EIS, would address actions pertaining to waste accumulated in storage on site as a result of past Project activities as well as waste to be generated in the near term. The second EIS, this decommissioning and/or long-term stewardship EIS, would analyze various decommissioning and/or long-term stewardship alternatives and would include decontamination as well. It would also include the management of wastes generated by decommissioning and/or long-term stewardship actions. Because this second EIS addresses strategies that may be used to complete the WVDP and disposition the Center, DOE now intends that this EIS would replace the 1996 Cleanup and Closure EIS. (DOE issued an Advance Notice of Intent inviting preliminary public input to the scope of this EIS on November 6, 2001 [66 FR 56090].)

On February 1, 2002, the NRC published in the **Federal Register** (67 FR 5003) its Decommissioning Criteria for the West Valley Demonstration Project (M–32) at the West Valley Site; Final Policy Statement. The NRC decided that it would apply its License Termination Rule (10 CFR 20, Subpart E) as the decommissioning criteria for the WVDP and the decommissioning goal for the entire NRC-licensed site. The NRC intends to use this West Valley EIS to evaluate the environmental impacts of the various alternatives before deciding whether to accept the preferred alternative as meeting the criteria permitted by the License Termination Rule.

**Purpose and Need for Action**

DOE is required by the WVDP Act to decontaminate and decommission the tanks and facilities used in the solidification of the HLW, and any material and hardware used in connection with the WVDP, in accordance with such requirements as the NRC may prescribe. The NRC has prescribed its License Termination Rule as the decommissioning criteria for the WVDP. Therefore, DOE needs to determine the manner that facilities, materials, and hardware for which the Department is responsible are managed or decommissioned, in accordance with applicable Federal and State requirements. To this end, DOE needs to determine what, if any, material or structures for which it is responsible will remain on site, and what, if any, institutional controls, engineered barriers, or stewardship provisions would be needed.

NYSERDA needs to determine the manner that facilities and property for which NYSERDA is responsible, including the State-Licensed Disposal Area, will be managed or decommissioned, in accordance with applicable Federal and State requirements. To this end, NYSERDA needs to determine what, if any, material or structures for which it is responsible will remain on site, and what, if any, institutional controls, engineered barriers, or stewardship provisions would be needed. It is NYSERDA's intent to pursue termination of the existing 10 CFR Part 50 license for the Western New York Nuclear Service Center (currently held in abeyance) upon DOE's completion of decontamination and decommissioning under the WVDP Act in accordance with criteria prescribed by the NRC. NYSERDA plans to use the analysis of alternatives in the Decommissioning and/or Long-Term Stewardship EIS to support any necessary NRC or NYSDEC license or permit applications.

**Areas of Disagreement With Respect to Responsibilities**

DOE and NYSERDA currently do not agree on their respective responsibilities, including whether DOE is required under the WVDP Act to remediate the North Plateau groundwater plume and decommission the NDA, and which party is responsible for any long-term stewardship following the decommissioning actions required under the WVDP Act.

In accordance with their respective applicable legal requirements, DOE and NYSERDA each have unilateral decision-making authority for those actions for which they are responsible. DOE will determine the manner in which it will decommission Project facilities as required under the WVDP Act. NYSERDA will determine the manner in which non-Project facilities, not required to be decommissioned under the WVDP Act, will be managed.

**Potential Range of Alternatives**

DOE and NYSERDA intend to use the NRC's License Termination Rule and associated guidance provided in the NRC's Final Policy Statement as the framework to evaluate possible alternatives for decommissioning and/or long-term stewardship actions involving WVDP facilities, as well as decommissioning and/or long-term stewardship actions involving NYSERDA-controlled facilities and areas on the Center. In the Final Policy Statement, the NRC recognized that it does not have the regulatory authority to apply the License Termination Rule to the SDA, and said that a cooperative approach with the State will be utilized to the extent practical to apply the License Termination Rule in a coordinated manner.

As required by NEPA, the EIS will present the environmental impacts associated with the range of reasonable

alternatives to meet DOE's and NYSERDA's purposes and needs for action, and a no-action alternative. This range encompasses release of the Center for re-use under unrestricted and restricted conditions as allowed under the License Termination Rule. The EIS will present the health and environmental consequences of the alternatives in comparable form to provide a clear basis for informed decision making. DOE's and NYSERDA's preferred alternative will be identified in the Draft EIS. This Draft EIS will also include an evaluation of whether the alternatives would meet the NRC decommissioning criteria and other applicable requirements.

*Alternative 1—Unrestricted Site Release*

DOE and NYSERDA intend to evaluate an alternative that could satisfy the License Termination Rule criteria and permit termination of NYSERDA's NRC license without restrictions. DOE and NYSERDA are proposing that this alternative involve removal of WVDP and non-WVDP wastes, structures, and contaminated soils to the extent required so that the radiological criteria specified in 10 CFR 20.1402 can be met for Project and non-Project facilities and the balance of the 3,345-acre Center. This alternative includes exhumation and offsite disposal of waste and contaminated soils from the NDA and SDA on the South Plateau.

DOE and NYSERDA intend to evaluate the need for new onsite interim waste storage capacity under Alternative 1 for some waste types, such as Greater-Than-Class C waste, that may not be able to be disposed of in a time frame that would support timely implementation of this EIS alternative. Such an interim storage facility would remain under institutional control until the waste it contains is removed from the site. Following implementation of this alternative, including removal of any wastes in interim storage, the Center could be released without restrictions.

*Alternative 2—Partial Site Release without Restrictions*

DOE and NYSERDA intend to evaluate an alternative that could satisfy the radiological criteria specified in 10 CFR 20.1402 for facilities and areas on the North Plateau geographic area of the Center, including the North Plateau groundwater plume, as well as the balance of the 3,345-acre Center, with the exception of the NDA and SDA. This would include removal of WVDP and non-WVDP wastes, structures, and contaminated soils to the extent required so that the radiological criteria specified in 10 CFR 20.1402 can be met for the North Plateau. Appropriate infiltration controls would be evaluated for the NDA and the SDA. The NDA and SDA on the South Plateau would not be released but would be managed, monitored, and maintained under permit, license, or other appropriate regulatory oversight. With the exception of the NDA and SDA, the WVDP Project Premises and Center could be released without restrictions. DOE and NYSERDA also intend to evaluate the need for new onsite interim waste storage that may be required to support timely completion of this alternative.

*Alternative 3—Partial Site Release with Restrictions*

DOE and NYSERDA intend to evaluate an alternative that may permit release with restrictions of portions of the North Plateau geographic area and the balance of the 3,345-acre Center, with the exception of the NDA and SDA. DOE and NYSERDA are proposing that this alternative involve removal of wastes and structures to the extent technically and economically practical so that the radiological criteria specified in 10 CFR 20.1403 can be met for the North Plateau. This would involve in-place closure of the Process Building, Vitrification Facility, HLW Tank Farm, wastewater treatment facility lagoons, and the North Plateau contaminated groundwater plume in a manner that is protective of public health, safety, and the environment. Other ancillary North Plateau facilities would be removed. Appropriate infiltration controls would be evaluated for the NDA and the SDA. The application of institutional controls and engineered barriers would be required and evaluated. The NDA and SDA on the South Plateau would not be released but would be managed, monitored, and maintained under permit, license, or other appropriate regulatory oversight. With the exception of the NDA and SDA, the end state would be the release of the WVDP Project Premises and Center under restricted conditions. However, unimpacted and/or remediated areas of the Center could be considered for release without restrictions. DOE also intends to evaluate the need for new onsite interim HLW storage that may be required to support timely completion of this alternative.

*Alternative 4—Monitor and Maintain under Current Operations*

This alternative involves the continued management and oversight of the Center and all facilities located upon the Center property, including the WVDP, after DOE's implementation of its Record of Decision for the WVDP Waste Management EIS. No decommissioning decisions would be made nor actions taken to make progress toward decommissioning, including decontamination beyond the scope that DOE is currently performing. No facilities would be closed in place, but would be left in their current configuration and actively monitored and maintained as required by existing regulations to protect public, worker, and environmental health and safety. When required, remedial actions would be taken in response to any releases of contamination into the environment that may present a health and safety risk, such as would be experienced from the eventual failure of the underground HLW storage tanks. Under this alternative, no portion of the Project Premises or the Center would be released for any present or future use.

*Alternative 5—No Action (Walk Away)*

This alternative involves the cessation of all management and oversight of the Center and all facilities located upon the Center property, including the WVDP, immediately after implementation of DOE's Record of Decision for the WVDP Waste Management EIS. The Process Building, Waste Tank Farm, Vitrification Facility, North Plateau groundwater plume, NDA, SDA, and other smaller facilities would remain and would not be monitored or maintained. Unmitigated natural processes, including erosion, groundwater transport of contamination, and concrete degradation, would be assumed to occur. The purpose of evaluating this alternative is to establish the basis against which the environmental impacts from all other decommissioning and/or long-term stewardship alternatives are compared.

*Alternatives Considered But Eliminated From Further Evaluation*

DOE does not consider the use of existing structures or construction of new aboveground facilities at the WVDP for indefinite storage of Project and non-Project LLW and mixed low-level waste (MLLW) to be a reasonable alternative for further consideration. Under the Waste Management Programmatic Environmental Impact Statement (WMPEIS, DOE/EIS–0200–F) Record of Decision, DOE decided that sites such as the WVDP would ship their LLW and MLLW to other DOE sites that have disposal capabilities for these wastes. (This decision did not preclude the use of commercial disposal facilities as well.) The construction, subsequent maintenance, and periodic replacement over time of new facilities for indefinite onsite waste storage at West Valley

would be impractical from a cost, programmatic, health, and environmental standpoint. Thus, given the capacity to safely and permanently disposition LLW and MLLW in available off site facilities, DOE would not consider indefinite onsite waste storage in new or existing facilities to be a viable waste management alternative for its decommissioning actions at the WVDP. For similar reasons, NYSERDA would use available commercial facilities for disposal of any non-Project LLW and MLLW that it may generate, in lieu of incurring the costs of new construction.

**New Information To Be Evaluated**

As discussed above, the NRC published its Final Policy Statement prescribing decommissioning criteria for the WVDP on February 1, 2002, stating that NRC intends to apply its License Termination Rule (10 CFR 20.1401 *et seq.*) as decommissioning criteria in assessing the health and environmental impacts of decommissioning the WVDP facilities. DOE and NYSERDA will utilize the NRC's Final Policy Statement and the License Termination Rule as the benchmark to develop and analyze their decommissioning alternatives in the Decommissioning and/or Long-Term Stewardship EIS.

For the 1996 Draft Cleanup and Closure EIS, DOE and NYSERDA developed or modified a variety of analytical tools specifically for that document. DOE has continued to refine many of these analytical tools as a result of public comments received on the 1996 Draft Cleanup and Closure EIS and ongoing interactions with stakeholders and regulatory agencies such as the NRC. DOE and NYSERDA intend to apply these improved analytical tools to the preparation of the Decommissioning and/or Long-Term Stewardship EIS. To address significant issues such as erosion, for example, DOE and NYSERDA have developed a site-specific erosion model, with ongoing advice from NRC, and integrated that model into a revised performance assessment methodology, incorporating the use of sensitivity and uncertainty analyses.

There are also some additional areas where new information has or will be obtained specifically for the Decommissioning and/or Long-Term Stewardship EIS. This work includes updated site characterization and census data and the performance of a seismic reflection survey in the vicinity of the Center. This seismic reflection survey, performed in consultation with academic, government, and industry participants, will contribute to knowledge about the regional structural geology as it may relate to the WVDP and the Center.

Additional information that has become available since publication of the 1996 Draft Cleanup and Closure EIS includes DOE's WM PEIS and its associated Records of Decision. The WM PEIS analyzed on a national scale the centralization, regionalization, or decentralization of managing HLW, transuranic waste, low-level radioactive waste, mixed radioactive low-level waste (containing hazardous constituents), and non-wastewater hazardous waste.

**Potential Environmental Issues for Analysis**

DOE has tentatively identified the following issues for analysis in the Decommissioning and/or Long-Term Stewardship EIS. The list is presented to facilitate early comment on the scope of the EIS. It is not intended to be all-inclusive nor to predetermine the alternatives to be analyzed or their potential impacts.

- Potential impacts to the general population and on-site workers from radiological and non-radiological releases from decommissioning and/or long-term stewardship activities.
- Potential environmental impacts, including air and water quality impacts, caused by decommissioning and/or long-term stewardship activities.
- Potential transportation impacts from shipments of radioactive, hazardous, mixed, and clean waste generated during decommissioning activities.
- Potential impacts from postulated accidents.
- Potential costs for implementation and long-term stewardship of alternatives considered.
- Potential disproportionately high and adverse effects on low-income and minority populations (environmental justice).
- Potential Native American concerns.
- Irretrievable and irreversible commitment of resources.
- Short-term and long-term land use impacts.
- Ability of alternatives to meet the Comprehensive Environmental Response, Compensation and Liability Act risk range.
- Ability of alternatives to satisfy WVDP decommissioning criteria.
- Compliance with applicable Federal, State, and local requirements.
- Identification of Derived Concentration Guideline Limits, where appropriate.
- The influence of, and potential interactions of, any wastes remaining at the Center after decommissioning.
- Unavoidable adverse impacts.
- Issues associated with long-term site stewardship, including regulatory and engineering considerations, institutional controls, and land use restrictions, including the need for buffer areas.
- Long-term health and environmental impacts, including potential impacts on groundwater quality.
- Long-term site stability, including erosion and seismicity.
- Waste Incidental to Reprocessing.
- Disposition of wastes generated as a result of decommissioning and/or long-term stewardship activities.

**Other Agency Involvement**

*Nuclear Regulatory Commission:* NRC has the regulatory responsibility under the Atomic Energy Act for the Center, which is the subject of the NRC license issued to NYSERDA pursuant to 10 CFR part 50, with the exception of the SDA. The NRC license is currently in abeyance pending completion of the WVDP.

The WVDP Act specifies certain responsibilities for NRC, including: (1) Prescribing requirements for decontamination and decommissioning; (2) providing review and consultation to DOE on the Project; and (3) monitoring the activities under the Project for the purpose of assuring the public health and safety. NRC will participate as a cooperating agency under NEPA on the West Valley Decommissioning and/or Long-Term Stewardship EIS. NRC may adopt this EIS for determining that the preferred alternative meets NRC's decommissioning criteria, assuming that NRC will find the preferred alternative acceptable.

Notwithstanding the WVDP, NRC retains the regulatory responsibility for the non-DOE activity in the non-Project area and non-SDA area to the extent that contamination exists both on and offsite resulting from activities performed when the facility was operating under its NRC 10 CFR part 50 license. Following completion of the WVDP and reinstatement of the license, NRC will have the regulatory responsibility for authorizing termination of the license, should NYSERDA seek license termination.

*United States Environmental Protection Agency:* The United States Environmental Protection Agency (USEPA) will participate as a cooperating agency under NEPA on the West Valley Decommissioning and/or Long-Term Stewardship EIS. As a

cooperating agency, EPA will review the EIS and other documents developed by DOE in conjunction with NYSERDA to provide early input on the analyses of environmental impacts associated with the decommissioning alternatives to be analyzed.

*New York State Department of Environmental Conservation:* With respect to DOE proposed actions, NYSDEC will participate as a cooperating agency under NEPA on the West Valley Decommissioning and/or Long-Term Stewardship EIS. As a cooperating agency, NYSDEC will review the EIS and other documents developed by DOE in conjunction with NYSERDA to provide early input on the analyses of environmental impacts associated with the decommissioning alternatives to be analyzed, and as part of their regulatory responsibilities. NYSDEC will participate as an involved agency under SEQRA with respect to NYSERDA's proposed actions.

NYSDEC regulates the SDA through issuance of permits under 6 New York Codes, Rules and Regulations (NYCRR) Part 380 Rules and Regulations for Prevention and Control of Environmental Pollution by Radioactive Materials. NYSDEC also regulates hazardous and mixed waste at the Center pursuant to 6 NYCRR Part 370 Series. This includes permitting activities under Interim Status for RCRA regulated units and Corrective Action Requirements for investigation and if necessary, remediation of hazardous constituents from Solid Waste Management Units.

NYSDEC is also responsible for ensuring compliance with the 1992 joint NYSDEC/USEPA 3008 (h) [New York State Environmental Conservation Law, Article 27, Titles 9 and 13] Order issued to the DOE and NYSERDA. The Order required investigation of solid waste management units, performance of interim corrective measures, and completion of Corrective Measures Studies, if necessary. NYSDEC and EPA intend to accommodate the DOE's and NYSERDA's efforts to coordinate and integrate the EIS process pursuant to the Order.

**Public Scoping Meetings**

DOE and NYSERDA will hold two public scoping meetings on the Decommissioning and/or Long-Term Stewardship EIS at the Ashford Office Complex, located at 9030 Route 219 in the Town of Ashford, NY, from 7 to 9:30 p.m. on April 9 and April 10, 2003. The purpose of scoping is to encourage public involvement and solicit public comments on the proposed scope and content of the EIS. Requests to speak at the public meeting should be made by calling or writing the DOE Document Manager (*see* **ADDRESSES**, above). Speakers will be scheduled on a first-come, first-served basis. Individuals may sign up at the door to speak and will be accommodated as time permits. Written comments will also be accepted at the meeting. Speakers are encouraged to provide written versions of their oral comments for the record.

The meetings will be facilitated by a moderator. Time will be provided for meeting attendees to ask clarifying questions. Individuals requesting to speak on behalf of an organization must identify the organization. Each speaker will be allowed five minutes to present comments unless more time is requested and available. Comments will be recorded by a court reporter and will become part of the scoping meeting record.

These two public scoping meetings will be held during a public scoping comment period. The comment period begins with publication of this NOI and will formally close on April 28, 2003. Comments received after this date will be considered to the extent practical. Comments provided during scoping will be addressed in the revised draft Decommissioning and/or Long-Term Stewardship EIS. Written comments will be received during the scoping period either in writing, by facsimile, or by email to Mr. Daniel Sullivan, DOE Document Manager (*see* **ADDRESSES**, above, for contact information).

**Schedule**

The DOE intends to issue the draft Decommissioning and/or Long-Term Stewardship EIS as early as December 2003. A public comment period of up to 180 days will start upon publication of the EPA's **Federal Register** Notice of Availability. DOE will consider and respond to comments received on the draft Decommissioning and/or Long-Term Stewardship EIS in preparing the final EIS.

Comments received during the 1989 scoping process and from the public comment period on the 1996 Cleanup and Closure EIS (DOE/EIS–0226-D) will be considered in the Decommissioning and/or Long-Term Stewardship EIS.

**Public Reading Rooms**

Documents referenced in this Notice of Intent and related information are available at the following locations: Central Buffalo Public Library Science and Technology Department, Lafayette Square, Buffalo, New York 14203, (716) 858–7098; The Olean Public Library, 134 North 2nd Street, Olean, New York 14760, (716) 372–0200; The Hulbert Library of the Town of Concord, 18 Chapel Street, Springville, New York 14141, (716) 592–7742; West Valley Central School Library, 5359 School Street, West Valley, New York 14141, (716) 942–3261; Ashford Office Complex, 9030 Route 219, West Valley, New York 14171, (716) 942–4555.

Issued in Washington, DC on March 7, 2003.

**Beverly A. Cook,**

*Assistant Secretary, Environment, Safety and Health.*

[FR Doc. 03–6055 Filed 3–12–03; 8:45 am]

**BILLING CODE 6450–01–P**

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## DEPARTMENT OF ENERGY

### Bonneville Power Administration

**[BPA File No: SN–03]**

### Bonneville Power Administration's Proposed Safety-Net Cost Recovery Adjustment Clause Adjustment to 2002 Wholesale Power Rates

**AGENCY:** Bonneville Power Administration, Department of Energy.

**ACTION:** Notice of proposed safety-net cost recovery adjustment clause: public hearing, and opportunity for public review and comment.

**SUMMARY:** The Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act), 16 U.S.C. 839, provides that the Bonneville Power Administration (BPA) must establish and periodically review and revise its rates to recover, in accordance with sound business principles, the costs associated with the acquisition, conservation, and transmission of electric power, and to recover the Federal investment in the Federal Columbia River Power System (FCRPS) and other costs incurred by BPA.

On February 7, 2003, the BPA Administrator determined that the Safety-Net Cost Recovery Adjustment Clause (SN CRAC) triggered based upon a forecast of a 50 percent or greater chance of missing a payment to the U.S. Treasury or another creditor during this fiscal year. The triggering of the SN CRAC initiates an expedited hearing under section 7(i) of the Northwest Power Act, 16 U.S.C. 839e(a)(1). By this notice, BPA announces a proposed SN CRAC adjustment to BPA's Wholesale Power Rates for FY 2002–2006, which the Federal Energy Regulatory Commission (FERC) approved on an interim basis on September 28, 2001. *U. S. Department of Energy—Bonneville Power Admin.,* 96 F.E.R.C. ¶ 61,360 (2001).

**DATES:** Proposed hearing dates are supplied in **SUPPLEMENTARY INFORMATION,** Section I.A. below.

The period for public comment period closes on May 1, 2003.

**ADDRESSES:** Written comments should be submitted to: Bonneville Power Administration, P.O. Box 12999, Portland, Oregon 97212. Comments can also be sent electronically to: *comments@bpa.gov.* The documents will be available for public viewing after March 31, 2003. The documents are available at: *http://www.bpa.gov/power/psp/rates/RateCases/sn03/,* or in BPA's Public Information Center, BPA Headquarters Building, 1st Floor; 905 NE. 11th, Portland, Oregon, and will be provided to parties at the prehearing conference to be held on March 31, 2003, from 9 a.m. to 12 p.m., Room 223, 911 NE. 11th, Portland, Oregon. Mr. Byron G. Keep, Power Products, Pricing and Rates Manager, is the official responsible for the development of BPA's power rates.

**FOR FURTHER INFORMATION CONTACT:** Interested persons may call Cynthia Jones at (503) 230–5459 or Cain Bloomer at (503) 230–7443.

**SUPPLEMENTARY INFORMATION:**

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## Part I—Introduction and Procedural Background

### *A. Relevant Statutory Provisions Governing This Rate Proceeding*

Guidance regarding BPA ratemaking is provided by the Bonneville Project Act, 16 U.S.C. 832, the Flood Control Act of 1944, 16 U.S.C. 825s, the Federal Columbia River Transmission System Act, 16 U.S.C. 838, and the Northwest Power Act, 16 U.S.C. 839.

BPA's rates must be established to recover BPA's costs. In particular, section 7(a)(1), 16 U.S.C. 839e(a)(1), provides in part that:

> [s]uch rates shall be established and, as appropriate, revised to recover, in accordance with sound business principles, the costs associated with the acquisition, conservation, and transmission of electric power, including the amortization of the Federal investment in the Federal Columbia River Power System (including irrigation costs required to be repaid out of power revenues) over a reasonable period of years and the other costs and expenses incurred by the Administrator pursuant to this Act and other provisions of law.

Section 7(i) of the Northwest Power Act, 16 U.S.C. 839e(i), requires that BPA's rates be established according to certain procedures. These procedures include, among other things, publication of notice of the proposed rates in the **Federal Register**; one or more hearings conducted as expeditiously as practicable by a Hearing Officer; public opportunity for both oral presentation and written submission of views, data, questions, and argument related to the proposed rates; cross-examination; and a decision by the Administrator based on the record. This proceeding is governed by section 1010.9 of BPA's Procedures Governing *Bonneville Power Administration Rate Hearings,* 51 FR 7611 (1986) (Procedures). The Procedures implement the statutory section 7(i) requirements. Section 1010.7 of the Procedures prohibits *ex parte* communications. Special rules governing the rate proceeding may also be adopted at the prehearing conference. Documents will be filed and served electronically under procedures to be established by the Hearing Officer at the prehearing conference.

BPA's proposed SN CRAC adjustment is published in Part V. below. The study addressing the factors used to develop the SN CRAC adjustment is summarized in Part IV.

BPA will release its 2003 initial SN CRAC rate proposal on March 31, 2003, and expects to publish a final Record of Decision (ROD) on June 30, 2003. BPA will conduct a formal evidentiary rate hearing for parties. Entities interested in becoming parties to this proceeding must file petitions to intervene in order to participate in the formal hearing. (See Part III. for further details on becoming a party.) A proposed schedule for the formal hearing is set forth below. A final schedule will be established by the Hearing Officer at the prehearing conference.

*Prehearing/BPA Direct Case:* March 31.
*Clarification:* April 2.
*Motions to Strike:* April 4.
*Data Request Deadline:* April 4.
*Answers to Motions to Strike:* April 10.
*Data Response Deadline:* April 10.
*Field Hearing:* April 16.
*Parties file Direct Cases:* April 17.
*Clarification:* April 21.
*Motions to Strike:* April 22.
*Data Request Deadline:* April 22.
*Answers to Motions to Strike:* April 28.
*Data Response Deadline:* April 28.
*Close of Participant Comments:* May 1.
*Litigants file Rebuttal:* May 2.
*Clarification:* May 5.
*Motions to Strike:* May 7.
*Data Request Deadline:* May 7.
*Answers to Motions to Strike:* May 13.
*Data Response Deadline:* May 13.
*Cross-Examination:* May 15–16.
*Initial Briefs Filed:* May 20.
*Oral Argument:* May 23.
*Draft ROD issued:* June 12.
*Briefs on Exceptions:* June 17.
*Final ROD—Final Studies:* June 30.

BPA will conduct a public field hearing on April 16, 2003, in Portland, Oregon. The public field hearing will provide an opportunity for persons who are not parties in the formal rate hearing to have their views included in the official record. Written transcripts will be made of the field hearing. The field hearing is scheduled to begin at 6 p.m. Confirmation of this hearing date and the specific location will be announced on BPA's Web site at: *http://www.bpa.gov/power/psp/rates/RateCases/sn03/index.shtml* and through public advertising, or interested persons may call the telephone numbers listed in above the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

### *B. Background*

In May 2000, BPA completed its analysis and final proposal for FY 2002–2006 rates. On July 6, 2000, pursuant to section 7(a)(2) of the Northwest Power Act, 16 U.S.C. section 839e(a)(2), BPA's Power Business Line (PBL) filed its proposed wholesale power rates with the Federal Energy Regulatory Commission (FERC). On August 4, 2000, BPA filed a motion with FERC requesting that FERC stay the proceeding for 30 days. After requesting the stay, BPA reviewed the impact of the unexpected price increases in the wholesale power markets on the West Coast and their effect on PBL's power rate proposal.

BPA concluded that, in light of the unprecedented price spikes during the

summer of 2000, PBL's proposed cost-based rates for FY 2002–2006 would be far more attractive to customers than market alternatives, and, in fact, public utility customers requested purchase contracts for significantly more power than forecasted in the BPA's May 2000 final rate proposal. This resulted in total load obligations of about 3,200 aMW more than the existing system could supply.

After a public comment period, BPA notified rate case parties on October 6, 2000, that it intended to initiate a limited 7(i) proceeding to address increased load obligations and high market prices. On December 1, 2000, BPA announced its proposed amendments to the 2002 wholesale power rate adjustment proposal. *Proposed Amendments to 2002 Wholesale Power Rate Adjustment Proposal,* 65 FR 75272 (2000) (Amended Proposal). BPA filed an Amended Proposal rather than formally modifying the original rate proposal for two main reasons. First, rates needed to be in place by October 2001 and there was no assurance a full rate proceeding could have been conducted within the time remaining. Second, the Treasury payment analysis showed that secondary revenues, even with very conservative assumptions relative to the actual forward market, would very likely cover any cost overruns.

After BPA released its Amended Proposal, the forecast for starting rate period reserves dropped substantially. In addition, market prices rose significantly from BPA's December 2000 forecast. These rapid developments necessitated significant changes to the Amended Proposal. BPA began settlement discussions with rate case parties to attempt to forge a resolution to the matter. When BPA and many of the rate case parties reached a Partial Settlement Agreement, BPA filed a Supplemental Proposal reflecting the terms of the Partial Settlement Agreement. The Partial Settlement Agreement included three separate Cost Recovery Adjustment Clauses, allowing the adoption of a general approach to keep base rates low and deal with financial shortfalls though the CRACs rather than raise base rates. These tools gave BPA the risk mitigation necessary to have a sufficiently high Treasury Payment Probability (TPP). The three CRACs are the Load-Based (LB) CRAC which is designed to cover augmentation costs, the Financial-Based (FB) CRAC which is designed to cover net revenue, and the Safety-Net (SN) CRAC which is available if the likelihood of missing a Treasury payment or payment to any other creditor is 50 percent or greater despite the implementation of the LB and FB CRACs. On September 28, 2001, FERC granted interim approval of BPA's rate filing, *U.S. Department of Energy—Bonneville Power Admin.,* 96 FERC ¶ 61,360 (2001).

The forecasts included in the Supplemental Rate Proposal, and reflected in the TPP forecast, included two sources of revenue that would cover expense increases. The first revenue source was secondary sales from high market prices. Market prices were forecast to stay high through 2003 because the development of electrical infrastructure was expected to take up to two years of development to catch up with the high demand that BPA and the west coast was experiencing. Therefore, the initial two years of the rate period were expected to be supply-limited. The second revenue source was also tied to these high market prices. Credits toward BPA's Treasury payments based on fish-related costs (fish credits) and impacts on operations were expected to contribute significantly to total revenues through high market prices. These fish credits contribute to BPA's overall revenues through a credit against BPA's payment to the U.S. Treasury. When market prices are higher, the size of the credit available to BPA may increase. BPA's June 2001 forecasts for secondary energy prices and available credits during the rate period proved to be inaccurate when market prices dropped faster and to lower levels than forecasted. This resulted in lower-than-forecasted revenues for BPA in fiscal year 2002. Hydro production during FY 2002–2003 also has been well below forecasts. The lingering effects of the 2001 drought on FY 2002 and the poor hydro conditions in 2003 have contributed to the significant decline in BPA's revenues. Although the hydro conditions appeared to be about normal over the January-July 2002 period, BPA stored a significant amount of water to replenish the low reservoirs resulting from the 2001 drought. This need for storage resulted in less 2002 hydro production than was forecast.

In addition, both operating and non-operating cost increases, relative to the levels assumed in the rates that BPA filed with FERC, have contributed to BPA's eroding financial condition. These increases include: BPA internal operating costs; hydro system costs; Federal debt service, net interest expense and depreciation; Columbia Generating Station costs; Direct Service Industries, California Independent System Operator and California Power Exchange bad debt expenses; conservation costs; and an increase in benefits to residential and small farm customers of investor-owned utilities.

Faced with a deterioration of its overall financial condition, BPA sent a letter to rate case parties and other interested entities in the region on July 2, 2002, announcing the beginning of the Financial Choices public comment process. The Financial Choices process examined a variety of financial and program options for addressing PBL's FY 2003–2006 financial challenges. In this process, BPA described those financial challenges, the actions BPA already had taken to address the problem, and the financial outlook for the remainder of the rate period. Additionally, BPA identified a variety of potential financial alternatives that, separately or in combination, could form the basis of a solution to PBL's financial situation.

During the course of the process, BPA held ten public meetings and workshops with customers, public interest groups, tribes, and other interested persons to explain the nature of the problem, and to show program level costs and the potential effects of cost reductions. BPA also solicited suggestions to address its growing financial problem. The public comment period closed on September 30, 2002. As a result of the Financial Choices process, BPA made decisions to cut, eliminate, or defer certain costs and expenses. BPA issued a Financial Choices close-out letter to the region on November 22, 2002, outlining BPA's plan, in part, for meeting the PBL's financial challenges. The plan takes into consideration extensive public input BPA received during the Financial Choices public process. The actions BPA has taken, and will take, as described in the Financial Choices close-out letter, include the identification of $350 million in expense savings, expense deferrals, and other actions for the FY 2003–2006 period. These will be reflected in the program levels in BPA's Initial Proposal. An additional $500 million of other potential savings and deferrals are being pursued, but are uncertain since they largely involve actions by other parties in the region.

While BPA did not trigger the SN CRAC in November, by January 2003, worsening water conditions and a refined secondary revenue forecast increased the net revenue gap for the 2002–2006 rate period to $950 million. In February 2003, the Administrator determined that BPA had lower than a 50 percent probability of making its Treasury payment in September 2003. An SN CRAC adjustment became necessary to ensure that rates and revenues will be sufficient to recover

costs with a high degree of certainty over the remainder of the rate period.

**Part II—Purpose and Scope of Proceeding**

*A. Purpose of Proceeding*

Triggering SN CRAC starts an expedited section 7(i) hearing to establish changes in the amount, duration, and timing parameters of the FB CRAC, taking into account prevailing conditions. On February 7, 2003, the BPA Administrator determined that the SN CRAC triggered based upon a forecast of a 50 percent or greater chance of missing a payment to the U.S. Treasury or another creditor during this fiscal year.

*B. Scope of Proceeding*

1. Other Proceedings

a. *Power Business Line WP–02 Rate Case*. On July 6, 2000, BPA filed proposed wholesale power rate adjustments with FERC as noticed in the **Federal Register**. 16 U.S.C. 839e(a)(2). *Proposed Amendments to 2002 Wholesale Power Rate Adjustment Proposal*, 65 FR 75272 (2000). BPA supplemented its rate filing with FERC on June 29, 2001. The supplementation of the rate filing included three CRAC risk mitigation tools. On September 28, 2001, FERC granted interim approval to BPA's rates filing. *U.S. Department of Energy—Bonneville Power Admin.,* 96 FERC ¶61,360 (2001).

Pursuant to section 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record any material attempted to be submitted or arguments attempted to be made in the hearing which seek to in any way visit the appropriateness or reasonableness of BPA's decisions in the WP–02 rate hearing. These decisions include but are not limited to issues related to the Slice methodology and contract issues including the Slice audit.

b. *Transmission Business Line TR–04 Rate Proceeding*. On December 20, 2002, BPA's Transmission Business Line (TBL) published a **Federal Register** Notice announcing the initiation of a rate-setting process for the FY 2004–2005 period. TBL's Initial Proposal reflected a settlement reached between BPA and its transmission customers. The Initial Proposal contains certain assumptions regarding TBL's revenues and expenses over the rate period. Some of these assumptions have been used in developing aspects of the SN–03 proposal and are identified in the supporting documentation. BPA does not intend to revisit the underlying basis for TBL's assumptions. Pursuant to section 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record any material attempted to be submitted or arguments attempted to be made in the hearing which seek to in any way visit the appropriateness or reasonableness of BPA's decisions in the TR–04 rate hearing.

2. Financial Choices and Spending Levels

The Financial Choices process allowed extensive review and comment on PBL's costs.

In addition, the decisions made in the Financial Choices process implemented prudent cost management to enhance TPP while minimizing rate impacts. These decisions are reflected in assumptions regarding program spending levels in the SN–03 Initial Proposal. BPA does not intend to revisit in this proceeding the decisions made during the Financial Choices process, including decisions on program spending levels.

Pursuant to section 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record any material attempted to be submitted or arguments attempted to be made in the hearing which seek to in any way visit the appropriateness or reasonableness of BPA's decisions and other decisions made in Financial Choices on spending levels, as included in PBL's test period revenue requirement for FY 2003–2006. If, and to the extent, any re-examination of spending levels is necessary, that re-examination will occur outside of the rate case. Excepted from this direction on account of their variable nature, dependency on PBL's rate case models, or timing, are: (1) Forecasts of short-term purchase power costs; (2) capital recovery matters such as interest rate forecasts, scheduled amortization, depreciation, replacements, and interest expense; and (3) inter-business line expenses.

3. Fish and Wildlife Costs and Hydro Operations

In BPA's WP–02 Wholesale Power Rate Case, potential fish and wildlife costs were reflected probabilistically, based on 13 system configuration alternatives arrived at during the development of the Fish and Wildlife Funding Principles (Revenue Requirement Study Documentation, Volume 1, WP–02–FS–BPA–02A, Chapter 13). These alternatives were developed specifically to inform and guide PBL's Subscription Process and power rate-setting, keeping options open because those processes would be concluded prior to decisions being made on system reconfiguration to aid threatened and endangered salmon.

In December 2000, the National Marine Fisheries Service (NOAA Fisheries) issued a Biological Opinion on the operation and configuration of the FCRPS addressing threatened and endangered salmon. Also in December 2000, the U.S. Fish and Wildlife Service (FWS) issued a Biological Opinion on the operation and configuration of the FCRPS addressing Endangered Species Act listed sturgeon and bull trout. Implementation of the NOAA Fisheries Biological Opinion requires the Action Agencies (Corps of Engineers, Bureau of Reclamation, and BPA) to issue annual implementation plans and five-year prospective implementation plans as well as regular annual progress reporting on the success of the Action Agencies' implementation actions. On November 6, 2002, BPA, the Corps of Engineers, and the Bureau of Reclamation released the Final FY 2003–2007 Implementation Plan for the FCRPS. The Implementation Plan identifies and describes the specific measures that the three agencies plan to implement in FY 2003–FY2007 and addresses the actions called for in the NOAA Fisheries and FWS 2000 Biological Opinions for the FCRPS. The Implementation Plan forms the basis for fish-related hydro-operations assumptions and spending level assumptions in the Initial Proposal.

BPA is currently engaged in regional discussions regarding fish-related changes to hydro operations, which are being evaluated in a regional forum. The Northwest Power Planning and Conservation Council (Council) is evaluating these proposed changes in its mainstem rulemaking proceedings. Upon receipt of the Council's final recommendations, the Action Agencies, in coordination with NOAA Fisheries and FWS, may decide to implement changes to measures as outlined in the Action Agencies Implementation Plan. The proposed changes are included in the analysis used to prepare BPA's Initial Proposal. To the extent other decisions are made in these proceedings by the time BPA's Final ROD is prepared, those decisions will be included in the Final ROD.

BPA's fish and wildlife program spending levels are developed to implement not only the Action Agencies' Implementation Plan, but also a set of operational, habitat, harvest, and hatchery measures to protect, mitigate, and enhance non-ESA listed species affected by the FCRPS. When BPA initiated Financial Choices, fish and wildlife spending levels were presented

and comments were taken. Those spending levels, including expenses and capital, are reflected in the SN–03 Initial Proposal, but are currently under review by the Council. If BPA changes those levels based on recommendations by the Council prior to writing the Final Record of Decision (ROD), those changes will be reflected in the Final ROD.

Pursuant to section 1010.3(f) of BPA's Procedures, the Administrator directs the Hearing Officer to exclude from the record any material attempted to be submitted or arguments attempted to be made in the hearing which seek in any way to revisit the policy merits or wisdom of implementation of the Biological Opinion, or the related operations, assumptions, and program spending level forecasts included in BPA's rate proposal, as discussed above. The Implementation Plan and any subsequent modifications were and are developed through extensive public involvement and comment processes, and have been and will be adopted as policy pursuant to those separate processes.

*C. National Environmental Policy Act*

BPA is in the process of assessing the potential environmental effects of this proposed rate adjustment, consistent with the requirements of the National Environmental Policy Act (NEPA) and its implementing regulations. In its Business Plan Final Environmental Impact Statement, DOE/EIS–0183, June 1995 (Business Plan EIS), BPA evaluated the environmental impacts of a range of business structure alternatives that included, among other things, various combinations of power pricing and rate designs for BPA's power rates. In addition, the Business Plan EIS identifies various response strategies, such as raising firm power rates, that could be implemented to address revenue shortfalls. In August 1995, the BPA Administrator issued a Record of Decision (Business Plan ROD) that adopted the Market-Driven Alternative from the Business Plan EIS. This alternative was selected because, among other reasons, it is the alternative that best allows BPA to: (1) Recover costs through rates; (2) achieve strategic business objectives; (3) competitively market BPA's products and services; and (4) continue to meet BPA's legal mandates.

An initial review of this proposed rate adjustment indicates that it is consistent with these aspects of the Market-Driven Alternative. This rate proposal would result in rate levels similar to those resulting from the rate designs evaluated in the Business Plan EIS, and thus would not be expected to result in significantly different environmental impacts from those examined for the Market-Driven Alternative in the Business Plan EIS. Furthermore, implementation of this rate proposal would be consistent with the response strategy of raising firm power rates to generate necessary revenues that was identified for all alternatives in the Business Plan EIS and Business Plan ROD. Therefore, BPA expects that this rate proposal will fall within the scope of the Market-Driven Alternative that was evaluated in the Final Business Plan EIS and adopted in the Business Plan ROD, and that BPA thus may tier its decision under NEPA for the proposed rate adjustment to the Business Plan ROD.

**Part III—Public Participation**

*A. Distinguishing Between ''Participants'' and ''Parties''*

BPA distinguishes between ''participants in'' and ''parties to'' the hearings. Apart from the formal hearing process, BPA will receive comments, views, opinions, and information from ''participants,'' who are defined in the BPA Procedures as persons who may submit comments without being subject to the duties of, or having the privileges of, parties. Participants' written and oral comments will be made part of the official record and considered by the Administrator. Participants are not entitled to participate in the prehearing conference; may not cross-examine parties' witnesses, seek discovery, or serve or be served with documents; and are not subject to the same procedural requirements as parties.

Written comments by participants will be included in the record if they are received by May 1, 2003. This date follows the anticipated submission of BPA's and all other parties' direct cases. Written views, supporting information, questions, and arguments should be submitted to the address listed in Section I. of this Notice. In addition, BPA will hold a field hearing in Portland, Oregon on April 16, 2003. Participants may appear at the field hearing and present oral testimony. The transcripts of these hearings will be a part of the record upon which the Administrator makes his final rate decisions.

Persons wishing to become a party to BPA's rate proceeding must notify BPA in writing. Petitioners may designate no more than two representatives upon whom service of documents will be made. Petitions to intervene shall state the name and address of the person requesting party status and the person's interest in the hearing.

Petitions to intervene as parties in the rate proceeding are due to the Hearing Officer by 9 a.m. on March 26, 2003. The petitions should be directed to: Maya R. Ferry, Hearing Clerk—LP, Bonneville Power Administration, 905 N.E. 11th Ave., P.O. Box 12999, Portland, Oregon 97212.

Petitioners must explain their interests in sufficient detail to permit the Hearing Officer to determine whether they have a relevant interest in the hearing. Pursuant to Rule 1010.1(d) of BPA's Procedures, BPA waives the requirement in Rule 1010.4(d) that an opposition to an intervention petition be filed and served 4 days before the prehearing conference. Any opposition to an intervention petition instead may be made at the prehearing conference. Any party, including BPA, may oppose a petition for intervention. Persons who have been denied party status in any past BPA rate proceeding shall continue to be denied party status unless they establish a significant change of circumstances. All timely applications will be ruled on by the Hearing Officer. Late interventions are strongly disfavored. Opposition to an untimely petition to intervene shall be filed and received by BPA within two days after service of the petition.

*B. Developing the Record*

The record will include, among other things, the transcripts of all hearings, any written material submitted by the parties, documents developed by BPA staff, BPA's environmental analysis and comments accepted on it, and other material accepted into the record by the Hearing Officer. The Hearing Officer then will review the record, will supplement it if necessary, and will certify the record to the Administrator for decision. Given the need for the SN CRAC adjustment to be in place by October 1, 2003, the Administrator directs the Hearing Officer to conclude the hearing process no later than July 10, 2003 so as to allow BPA sufficient time to comply with 18 CFR part 300.

The Administrator will develop final proposed rates based on the entire record, including the record certified by the Hearing Officer, comments received from participants, other material and information submitted to or developed by the Administrator, and any other comments received during the rate development process. The basis for the final proposed rates first will be expressed in the Administrator's Draft ROD. Parties will have an opportunity to respond to the Draft ROD as provided in BPA's Procedures. The Administrator

will serve copies of the Final ROD on all parties. At the conclusion of the rate proceeding, BPA will file the SN–03 rate proposal with FERC for confirmation and approval.

BPA must continue to meet with customers in the ordinary course of business during the rate case. To comport with the rate case procedural rule prohibiting *ex parte* communications, BPA will provide notice of meetings involving rate case issues for participation by all rate case parties. Parties should be aware, however, that such meetings may be held on very short notice and they should be prepared to devote the necessary resources to participate fully in every aspect of the rate proceeding. Consequently, parties should be prepared to attend meetings every day during the course of the rate case.

**Part IV—BPA's Proposed Solution to the Cost Recovery Problem**

*A. Introduction*

As noted earlier, the Administrator determined that in spite of the significant cost cutting identified in the Financial Choices process, BPA has less than a 50 percent probability of meeting its Treasury payment obligations. On February 7, 2003, the Administrator sent a letter to rate case parties and other interested individuals explaining the continued deterioration of BPA's financial situation and announcing the triggering of the SN CRAC process.

BPA is proposing a three-year variable SN CRAC adjustment to power rates, which has a cap limiting the amount of revenues that can be collected each year. Under BPA's proposal, in August of each year, the level of SN CRAC for the next fiscal year will be determined, based on the then-current forecast of PBL's accumulated net revenues (ANR) for the end of the then-current fiscal year. The annual average expected value for the SN CRAC is about 30 percent above May 2000 base rates. The adjustment in a particular year could be as high as 41 percent or as low as zero, depending on PBL's financial condition as reflected in BPA's forecasted ANR.

These percentages do not reflect the overall rate increase customers can expect after the implementation of PBL's proposed SN CRAC because of the interaction among the three CRACs. The total power rate customers will pay will reflect changes to the LB and FB CRACs and the proposed SN CRAC. While it will vary, the resulting total rate is expected to be about 16 percent, on average, above FY2003 rates (which include LB and FB CRACs) for the remainder of the rate period.

*B. Safety-Net Cost Recovery Adjustment Clause Design*

BPA's SN CRAC proposal uses a Treasury payment probability measure different from that used in prior rate cases. BPA is concerned that a rate increase of the magnitude necessary to achieve the 80–88 percent five-year TPP standard used to establish the WP–02 rates is not sustainable in the current economy. Therefore, BPA is proposing to relax the standard, but at the same time provide sufficient assurance that by the end of the rate period BPA will have a high probability of making its payment to the U.S. Treasury. This assurance will be met in part by an additional criterion that the PBL expected net revenues for the entire rate period (FY 2002–2006) will be zero or greater. For the next general rate proceeding, BPA intends to return to its long-term goal of 88 percent TPP.

In January 1993, BPA adopted a 10-Year Financial Plan that included a TPP standard for use in setting BPA's rates. At that time, BPA typically had two-year rate periods and the TPP standard called for achieving a 95 percent probability that BPA would make all of its Treasury payments in that rate period on time and in full. BPA's 1996 rates were set to cover a five-year period, and in that process, the 95 percent probability was translated into an 88 percent five-year TPP that provided comparable assurance of timely repayment. The Fish and Wildlife Funding Principles guided the development of power rates for the FY 2002–2006 rate period. In the Fish and Wildlife Funding Principles, the standard for that five-year TPP was allowed to be in the range of 80 to 88 percent in light of the economic burden that achieving the full 88 percent TPP would impose on the Pacific Northwest region.

Specifically for the SN CRAC proceeding, BPA is proposing to use three payment probability criteria in lieu of the long-term goal, mentioned above, including the net revenue criterion. BPA does not intend to replace the 88 percent standard, but is proposing these three alternative standards in this SN–03 process in order to meet the twin goals of moving toward a financially healthier BPA while limiting the effect on a fragile economy. The first criterion is a 50 percent probability that BPA can make all of its Treasury payments in the FY 2004–2006 three year period. This is relaxed from 87.5 percent, which is the three-year probability that corresponds to 80 percent for a five-year period. The second standard, a Treasury Recovery Probability (TRP), requires that the calculated probability that BPA will be able to make all of its FY 2006 payments to the U.S. Treasury, including repayment of any amounts missed in years FY 2003–2005, is at least 80 percent. The third standard requires that net revenues over the FY 2002–2006 period are zero or greater. These criteria provide a high level of assurance that BPA's obligations to the U.S. Treasury will be satisfied by the end of FY 2006.

*C. BPA's Proposal*

The proposed SN CRAC design is similar to the existing FB CRAC as described in the 2002 GRSPs. The proposed SN CRAC is a temporary, upward adjustment to posted power rates based on the level of end-of-year ANR in the generation function, as defined in the section on the FB CRAC in the 2002 GRSPs. The August forecast of ANR or each fiscal year from 2003–2005 is compared to the SN CRAC threshold applicable to that fiscal year. If the forecasted ANR is below the threshold, an SN CRAC rate adjustment will be implemented to collect either the amount of the difference between the forecasted ANR and the threshold, or an annual cap, whichever is smaller. The proposed SN CRAC rate adjustment will be determined annually, go into effect on October 1 of each year, and be in effect for the remainder of that fiscal year. The adjustment will be applied to the appropriate rates for the 12-month fiscal year.

The ANR threshold levels for the remaining three years of the rate period are: $-400 million for FY 2004, $−140 million for FY 2005, and $5 million for 2006. The annual cap is $470 million.

Consistent with the 2002 GRSPs, the SN CRAC applies to power customers under the following firm power rate schedules:

1. PF Preference (PF excluding Slice), PF Exchange Program, and PF Exchange Subscription;
2. Industrial Firm Power (IP–02), including purchases under the Industrial Firm Power Targeted Adjustment Charge (IPTAC) and Cost-Based Index Rate;
3. Residential Load (RL–02), including both actual power deliveries and the monetary benefits of any Residential Exchange Program (REP) Settlement;
4. New Resource Firm Power (NR–02); and
5. Subscription purchases under Firm Power Products and Services (FPS).

The SN CRAC does not apply to:

1. Pre-Subscription Contracts (to the extent prohibited by contract);

2. Seasonal and Irrigation Mitigation Contracts; or

3. Slice Purchases.

*D. Summary of Supporting Study*

There will be one study with seven chapters supporting BPA's SN CRAC proposal. Chapter 1 describes PBL's financial conditions and an overview of BPA's SN CRAC proposal. Chapter 2 describes the methodology for PBL's loads and sales forecasts. It also includes the assumptions used in the development of the hydro regulation study and other resources. Chapter 3 contains BPA's generation revenue requirement including a forecast of generation expenses. Chapter 4 describes the analysis that quantifies PBL's net revenue risk. Chapter 5 describes the methodology and resulting forecast of PBL's secondary revenues. Chapter 6 contains PBL's revenue forecast at current and proposed rates, and chapter 7 describes the Tool Kit model, the SN CRAC proposed design and the associated GRSPs.

**Part V—The Amended 2002 GRSPs**

*Safety-Net Cost Recovery Adjustment Clause (SN CRAC)*

The SN CRAC applies to power purchases under the following firm power rate schedules: PF [Preference (excluding Slice), Exchange Program and Exchange Subscription]; Industrial Firm Power (IP–02), including purchases under the Industrial Firm Power Targeted Adjustment Charge (IPTAC) and Cost-Based Index Rate; Residential Load (RL–02) (including both actual power deliveries and the 900 aMW of monetary benefits under the financial portion of any REP Settlement, buy-downs and load reduction agreements); New Resource Firm Power (NR–02); and subscription purchases under Firm Power Products and Services (FPS). The SN CRAC does not apply to power purchases under Pre-Subscription contracts to the extent prohibited by such contracts, to BPA's current contractual obligations for Seasonal and Irrigation Mitigation sales including for any eligible customer that converts from Slice to another BPA product, or to purchases under the PF Slice Rate.

*A. Formula for Calculation of the Safety-Net Cost Recovery Adjustment Clause*

By August of each fiscal year (FY 2003–2005) immediately prior to each fiscal year of the remainder of the rate period (*i.e.*, FY 2004–2006), a forecast of that end-of-year Accumulated Net Revenue (ANR) will be completed. BPA will compare the forecasted ANR to the SN CRAC Threshold applicable to that year to determine the SN CRAC to be implemented. If the ANR at the end of the forecast year falls below the SN CRAC Threshold applicable to that fiscal year, an SN CRAC rate adjustment will be implemented. That SN CRAC rate adjustment will go into effect beginning in October of the upcoming fiscal year (FY 2004–2006).

The Revenue Amount will be determined by the following formula:

Revenue Amount is the lower of:

SN CRAC Threshold minus forecasted ANR; or

The annual Maximum Planned Recovery Amount, shown in Table A below.

Where Revenue Amount is the amount of additional revenue that an adjustment in rates under SN CRAC is intended to generate during the one year period that the rate adjustment is effective.

Where SN CRAC Threshold is the ANR level below which a rate adjustment is determined. The thresholds specified for the end of FY 2003, 2004, and 2005 are shown in Table A.

Where ANR is generation function net revenues, as accumulated since 1999, at the end of each of the fiscal years 2003–2005. The forecast of ANR through the end of each fiscal year will be calculated and used to determine if the threshold has been reached and the Revenue Amount needed. Net revenues for any given fiscal year are accrued revenues less accrued expenses, in accordance with Generally Accepted Accounting Principles, with the following two exceptions. First, for purposes of determining if the SN CRAC threshold has been reached, actual and forecasted expenses will include BPA expenses associated with Energy Northwest debt service as forecasted in the WP–02 Final Studies. Second, the impact of adopting Financial Accounting Standard 133, Accounting for Derivative Instruments and Hedging Activities, will not be considered in determining if the SN CRAC threshold has been reached. Only generation function actual and forecasted revenues and expenses that are associated with the production, acquisition, marketing, and conservation of electric power, will be included in determinations under the SN CRAC. Accrued revenues and expenses of the transmission function are excluded. Impacts of forecasted revenues, positive or negative, from contractual true-up pursuant to the Slice Agreement shall be included in the revenue forecast when determining the SN CRAC.

Where Maximum Planned Recovery Amount is the maximum annual amount planned to be recovered through the SN CRAC.

TABLE A

[DOLLARS IN MILLIONS]

| End of fiscal year | SN CRAC threshold (ANR) | Maximum Planned Recovery Amount (Beginning October) |
|---|---|---|
| 2003 | $ − 400 | $470 |
| 2004 | − 140 | 470 |
| 2005 | 5 | 470 |

Once the Revenue Amount is determined, that amount will be converted to the SN CRAC Percentage. The SN CRAC Percentage is the percentage adjustment in customers' rates (not including LB CRAC or FB CRAC) in each of the firm power rate schedules listed above. This percentage will be applied to generate the additional SN CRAC revenue.

The SN CRAC Percentage will be determined by the following formula:

SN CRAC Percentage =

Revenue Amount

Divided by SN CRAC Revenue Basis

SN CRAC Revenue Basis is the total generation revenue (not including LB CRAC or FB CRAC) for the loads subject to SN CRAC for the fiscal year in which the SN CRAC implementation begins, based on the then most current revenue forecast. Each non-Slice product's total charge for energy, demand, and load variance will be adjusted by this CRAC percentage amount.

Payment under the SN CRAC rate adjustment will be due monthly from November (for the October billing period) through October of the following year.

In August prior to the beginning of each fiscal year of the rate period (FY 2004–2006), the Administrator will compare the ANR forecast at the end of that current fiscal year to that year SN CRAC Threshold. The customers will be billed in accordance with the SN CRAC adjustment.

Each customer will be notified, on or about September 1st, of the percentage adjustment in rates due to the SN CRAC. The rates used to calculate the customers' bills for the following October through September for FY 2004–2006, will reflect the SN CRAC adjustment.

*B. Retriggering of the SN CRAC*

The SN CRAC will be retriggered if the Administrator determines that, after implementation of the FB CRAC, the currently active SN CRAC, and any forecast of Augmentation True-Ups, either of the following conditions exists:

• BPA forecasts a 50 percent or greater probability that it will nonetheless miss a payment to the U.S. Treasury or other creditor, or

• BPA has missed a payment to the U.S. Treasury or has satisfied its obligation to the U.S. Treasury but has missed a payment to any other creditor.

A retriggering of the SN CRAC will result in an upward adjustment to posted power rates listed above by modifying the SN CRAC parameters that are currently in use. BPA will propose changes to the SN CRAC parameters that will, to the extent market and other risk factors allow, achieve a high probability that the remainder of Treasury payments during the FY 2002–2006 rate period will be made in full. BPA's proposal could include changes to the Revenue Amount, the Cap, the Threshold, the duration (the length of time the SN CRAC would be in place, which could be more than one year), and the timing of collection. The additional revenue to be generated by the SN CRAC will be collected through a percentage adjustment in applicable rates and a commensurate decrease in the financial portion of the Residential Exchange Settlement. In addition to the revenue generated by the SN CRAC, BPA's payments for IOU load reductions will be reduced in accordance with contractual provisions.

a. *SN CRAC Notification Process.* At the time the Administrator determines that the SN CRAC has retriggered, BPA will send written notification of the determination to customers that purchase power under rates subject to the SN CRAC and to interested parties. Such notification shall include the documentation used by BPA to determine that the SN CRAC has retriggered, the amount of any forecast shortfall, and the time and location of a workshop on the SN CRAC.

The purpose of the SN CRAC workshop will be to discuss with customers and interested parties the cause of the shortfall, and any proposed changes to the SN CRAC that will achieve a high probability that the remainder of Treasury payments during the FY 2002–2006 rate period will be made on time. In determining which proposal to include in its initial proposal in the SN CRAC Section 7(i) proceeding, BPA will give priority to prudent cost management and other options that enhance Treasury Payment Probability while minimizing changes to the SN CRAC.

b. *SN CRAC Hearing Process.* As soon as practicable after a determination that the SN CRAC has retriggered, BPA will publish a **Federal Register Notice** initiating an expedited hearing process to be conducted in accordance with Section 7(i) of the Northwest Power Act. The hearing shall be completed within 40 days, unless a different duration is agreed to by BPA and the parties. Upon completion of such hearing, BPA will submit the following documentation to FERC in support of a request for review and confirmation: Statements A through F from the 2002–2006 BPA Wholesale Power Rate Adjustment Proceedings, Separate Accounting Analyses, current and revised revenue tests, the proposed revisions to the SN CRAC parameters and the administrative record compiled by BPA in the SN CRAC proceeding.

The changes to the SN CRAC parameters shall take effect 60 days from filing with FERC unless FERC orders otherwise prior to that time.

Issued in Portland, Oregon, on March 6, 2003.

**Stephen J. Wright,**

*Administrator and Chief Executive Officer, Bonneville Power Administration.*

[FR Doc. 03–6091 Filed 3–12–03; 8:45 am]

BILLING CODE 6450–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. AC03–20–000]**

### American Electric Power Service Corporation; Notice of Filing

March 7, 2003.

Take notice that on January 29, 2003, American Electric Power Service Corporation (AEP) tendered for filing with the Federal Energy Regulatory Commission (Commission) a letter addressed to John M. Delaware, Chief Accountant of the Commission, requesting authorization to retain and recognize as a regulatory asset Regional Transmission Organization (RTO) formation/integration cost deferrals.

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, 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 motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may 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 toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. 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 under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

*Comment Date:* 20 days from the date of publication in the **Federal Register**.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6000 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP03–288–000]**

### ANR Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

March 6, 2003.

Take notice that on February 28, 2003, ANR Pipeline Company (ANR) tendered for filing, as part of its FERC Gas Tariff, Second Revised Volume No. 1 (Tariff), the following tariff sheets proposed to become effective March 1, 2003:

Fifty-Fifth Revised Sheet No. 8.
Fifty-Fifth Revised Sheet No. 9.
Fifty-Fourth Revised Sheet No. 13.
Sixty-Sixth Revised Sheet No. 18.

ANR states that the above-referenced tariff sheets are being filed to implement recovery of approximately $3.1 million of above-market costs that are associated with its obligations to Dakota Gasification Company (Dakota). ANR proposes a reservation surcharge applicable to its part 284 firm transportation customers to collect ninety percent (90%) of the Dakota costs, and an adjustment to the maximum base tariff rates of Rate

Schedule ITS and overrun rates applicable to Rate Schedule FTS–2, so as to recover the remaining ten percent (10%). ANR advises that the proposed changes would increase current quarterly Above-Market Dakota Cost recoveries from $2,326,128 to $3,091,394.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Intervention and Protest Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6030 Filed 3–12–03; 8:45 am]

**BILLING CODE 6717–01–P**

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. RP03–289–000]**

## ANR Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

March 6, 2003.

Take notice that, on February 28, 2003, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, Sixty-Seventh Revised Tariff Sheet No. 18, proposed to become effective March 1,003.

ANR states that the above-referenced tariff sheet is being filed to implement the annual reconciliation of the recovery of its Above-Market Dakota Costs, as required by its tariff recovery mechanism. ANR advises that the filing proposes a reservation surcharge adjustment of $0.012 applicable to its currently effective, firm service Rate Schedules. Pursuant to this surcharge, ANR proposes to recover, over the twelve month period of March 1, 2003 to February 29, 2004, the $645,001 of Above-Market Dakota Cost under collections, inclusive of interest, which are reflected in the filing.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6031 Filed 3–12–03; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. RP03–290–000]**

## ANR Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

March 6, 2003.

Take notice that on February 28, 2003, ANR Pipeline Company (ANR) tendered for filing, as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets to be effective April 1, 2003:

Nineteenth Revised Sheet No. 19.
Ninth Revised Sheet No. 68H.

ANR states that the above-referenced tariff sheets are being filed to comply with the annual re-determination of the levels of ''Transporter's Fuel Use (%)'', as required by ANR's currently effective tariff. In accordance with Section 1.68 of the General Terms and Conditions in ANR's tariff, the annual re-determined percentages are based upon ANR's most recent three (3) calendar years' experience of compressor fuel usage (2000, 2001 and 2002), and most recent four (4) years' experience of Lost and Unaccounted For gas (1999, 2000, 2001 and 2002).

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6032 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. CP03–57–000]**

## El Paso Natural Gas Company; Notice of Application

March 7, 2003.

Take notice that on February 27, 2003, El Paso Natural Gas Company (El Paso), P. O. Box 1087, Colorado Springs, Colorado 80944 filed in Docket No. CP03–57–000, an application pursuant to sections 7(b) and 7(c) of the Natural Gas Act (NGA), as amended, and part 157 of the regulations of the Federal Energy Regulatory Commission (Commission), for permission and approval to abandon, by removal, certain existing mainline compression facilities, with appurtenances, and for a certificate of public convenience and necessity authorizing the construction and operation of new mainline compression facilities, with appurtenances, all located at El Paso's existing Bondad Compressor Station in La Plata County, Colorado (Bondad Expansion Project), all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing is available for review at the Commission or may 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 toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

El Paso states that it is proposing to undertake the following activities at its existing Bondad Compressor Station located in La Plata County, Colorado:

(1) Abandon two existing Solar Centaur T4000 simple cycle gas turbine engines and one Solar Centaur T3550 simple cycle gas turbine engine which have a combined horsepower rating of 10,740 (ISO), with appurtenant equipment.

(2) Replace the three existing Solar Centaur simple cycle gas turbine engines with two Solar Centaur 50–T6100L simple cycle gas turbine engines and one Solar Centaur 50S–T6100 SoLoNox simple cycle gas turbine engine, with appurtenances, which have a combined horsepower rating of 18,390 (ISO).[1] The Solar Centaur 50S–T6100 simple cycle gas turbine engine is equipped with air emission-lowering SoLoNox technology.

(3) Restage the three existing compressor units at the Bondad Compressor Station. The compressors will be disassembled and the single stage aerodynamic assembly of each compressor will be removed and exchanged with a two stage assembly.

In its application, El Paso states that it has designed the Bondad Expansion Project to permit El Paso to offer additional firm transportation capacity on a defined receipt/delivery point basis of up to 140,000 Mcf per day, while continuing to meet the current transport capacity needs of its existing shippers (approximately 585.5 MMcf per day). According to El Paso, this additional firm capacity will be offered from receipt points upstream of the Bondad Compressor Station to a proposed new delivery point located near its existing Blanco Compressor Station located in San Juan County, New Mexico. Since this new increment of firm capacity is only available to the Blanco area, El Paso states that the project will not create additional mainline capacity out of the San Juan Basin.

In support of the Bondad Expansion Project, El Paso states that it has entered into a binding firm Transportation Service Agreement with BP Energy Company (BP) for the transportation of gas on El Paso's existing Ignacio Lines from any point of receipt in the Bondad Pooling Area to the Blanco Delivery Point. El Paso also states that the contract demand under this TSA equals the proposed 140,000 Mcf per day increase in design capacity for transportation on the Bondad System.

El Paso states that the cost for the Bondad Expansion Project is approximately $7,307,700 and El Paso plans to place the proposed facilities in service by April 1, 2004.

Any questions concerning this application may be directed to Robert T. Tomlinson, Director, Regulatory Affairs, El Paso Natural Gas Company, P. O. Box 1087, Colorado Springs, Colorado, 80944, at (719) 520–3788 or fax (719) 520–4318; or to Judy A. Heineman, Vice President and General Counsel, El Paso Corporation—Western Pipelines Division, P. O. Box 1087, Colorado Springs, Colorado, 80944, at (719) 520–4829 or fax (719) 520–4898.

[1] Note that El Paso is seeking abandonment authorization for the three units that will be replaced. El Paso will exchange the existing units for the three units with the manufacturer.

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 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) by the comment date, below. 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.

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 under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

*Comment Date:* March 28, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6001 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP03–298–000]**

### Great Lakes Gas Transmission Limited Partnership; Notice of Request for Emergency Waiver

March 7, 2003.

Take notice that on March 6, 2003, Great Lakes Gas Transmission Limited Partnership (Great Lakes) filed a request for emergency waiver of its tariff to be effective during the curtailment period resulting from a recent force majeure event on Great Lakes' system. Great Lakes declared force majeure on its system because of a major failure on one of its compressor units located at a Shelvin, Minnesota compressor station. The event resulted in curtailment of firm transportation service offered under Great Lakes' FERC Gas Tariff.

Great Lakes states that it provides firm transportation to shippers some of which serve communities and industrial customers that have no other natural gas pipeline facilities accessing their areas (sole source customers) and that curtailment of these customers could potentially result in adverse consequences to these shippers.

Great Lakes states that under section 11.4 of the general terms and conditions of its Tariff, all Category A firm shippers are curtailed equally pro-rata based upon scheduled nominations. Great Lakes states further that its Tariff does not address service to a shipper serving a sole source customer except insofar as that shipper meets the definitions for Category A.

Great Lakes states that the requested waiver will permit Great Lakes to ensure service to those communities and industrial customers whose supply must be delivered by means of Great Lakes' facilities and that the waiver will have a *de minimus* impact on the remaining shippers whose capacity is affected by the force majeure event and whose capacity is curtailed.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's rules and regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. Comments, protests and interventions 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 under the ''e-Filing'' link.

*Comment Date:* March 14, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6005 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP03–256–001]**

### Honeoye Storage Corporation; Notice of Proposed Change in FERC Gas Tariff

March 6, 2003.

Take notice that on February 28, 2003 Honeoye Storage Corporation (Honeoye) tendered for filing as part of its FERC Gas Tariff, First Revised Volume 1A, a revised tariff sheet to be effective April 1, 2003. The revised tariff sheet is designated as:Second Revised Sheet No. 105 Superseding First Revised Sheet No. 105

Honeoye states that the purpose of the filing is to substitute the above reference tariff sheet to correct an incorrect heading that was contained in its filing made on February 14, 2003. The text of Tariff Sheet No.105 is unchanged. Honeoye states that copies of the filing are being mailed to Honeoye's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 11, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6029 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP01–422–004]**

### Kern River Gas Transmission Company; Notice of Compliance Filing

March 6, 2003.

Take notice that on February 28, 2003, Kern River Gas Transmission Company (Kern River) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets, to be effective May 1, 2003:

Sixth Revised Sheet No. 5–A.
Third Revised Sheet No. 109.
Third Revised Sheet No. 110.
Second Revised Sheet No. 110–A.
Original Sheet No. 110–A.1.
Second Revised Sheet No. 110–B.
First Revised Sheet No. 110–C.

Kern River states that the purpose of this filing is to comply with the Preliminary Determination on Non-Environmental Issues dated February 27, 2002, in Docket No. CP01–422.

Kern River states that it has served a copy of this filing upon its customers, interested state regulatory commissions, and intervenors on the official service list for Docket No. CP01–422.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission,

888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Protest Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6019 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. CP03–51–000]**

### Natural Gas Pipeline Company of America; Errata Notice

March 6, 2003.

In the Commission's Notice of Application issued February 24, 2003, in the above proceeding, on page 1, paragraph 3 of the notice, in the last sentence, change ''requests'' to ''does not request''. The sentence should read: ''Natural states that the cost of the project is approximately $2.8 million and Natural does not request rolled-in rate treatment for the new facilities''.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6020 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 2852]**

### New York State Electric & Gas Corporation; Notice of Authorization for Continued Project Operation

March 6, 2003.

On February 27, 2001, New York Electric & Gas Corporation, licensee for the Keuka Project No. 2852, filed an application for a nonpower license pursuant to the Federal Power Act (FPA) and the Commission's regulations thereunder. Project No. 2852 is located between Waneta Lake and Lamoka Lake impoundments, and Keuka Lake in Steuben and Schuyler Counties, New York.

The license for Project No. 2852 was issued for a period ending February 28, 2003. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 2852 is issued to New York State Electric & Gas Corporation for a period effective March 1, 2003, through February 29, 2004, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before March 1, 2004, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that New York State Electric & Gas Corporation is authorized to continue operation of the Keuka Project No. 2852 until such time as the Commission acts on its application for subsequent license.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6027 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 2659–011]**

### PacifiCorp; Notice of Meeting To Discuss Settlement Negotiations and Surrender Application

March 6, 2003.

a. *Date and Time of Meeting:* March 17, 2003; 10 a.m. Pacific Standard Time.

b. *Place:* Conference Call.

c. *FERC Contact:* Bob Easton at *robert.easton@ferc.gov* or (202) 502–6045.

d. *Purpose of Meeting:* PacifiCorp and various stakeholders have requested a meeting with Commission staff to discuss ongoing settlement negotiations which are anticipated to result in filing of a surrender application for the Powerdale Project (P–2659–011) in late March or early April 2003. The project is located on the Hood River in Hood River, Oregon.

e. *Proposed Agenda:* (1) Introduction of participants, (2) PacifiCorp/stakeholder presentation on negotiations and/or application, (3) Discussion, and (5) Close Meeting.

f. All local, state, and federal agencies, Indian tribes, and other interested parties are invited to join the conference call. Please call Bob Easton at (202) 502–6045 at least one day in advance for instructions on how to join the conference call.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6026 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP99–518–036]**

### PG&E Transmission, Northwest Corporation; Notice of Proposed Change in FERC Gas Tariff

March 6, 2003.

Take notice that on March 3, 2003, PG&E Gas Transmission, Northwest Corporation (GTN) tendered for filing Fifth Revised Sheet No. 15, Second Revised Sheet No. 19, and First Revised Sheet No. 20 to be part of its FERC Gas Tariff, Second Revised Volume No. 1–A. GTN states that these sheets are being filed to reflect the implementation of four negotiated rate agreements and the removal of three negotiated rate agreements that have expired. GTN requests that the Commission accept the proposed tariff sheets to be effective March 1, 2003.

GTN further states that a copy of this filing has been served on GTN's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 17, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6037 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP99–513–024]**

### Questar Pipeline Company; Notice of Tariff Filing

March 6, 2003.

Take notice that on March 3, 2003, pursuant to 18 CFR 154.7 and 154.203, and as provided by section 30 (Negotiated Rates) to the General Terms and Conditions of part 1 of Questar Pipeline Company's (Questar) FERC Gas Tariff, Questar submitted a tariff filing to implement negotiated-rate contracts for Dominion Exploration & Production, Inc., and BP Energy Company as authorized by Commission orders issued October 27, 1999, and December 14, 1999, in Docket Nos. RP99–513, *et al.*

Questar requested waiver of 18 CFR 154.207 so that Twenty-Fifth Revised Sheet No. 7 to First Revised Volume No. 1 of its FERC Gas Tariff may become effective March 1, 2003.

Questar states that a copy of this filing has been served upon all parties to this proceeding, Questar's customers, the Public Service Commission of Utah and the Public Service Commission of Wyoming.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 17, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6036 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP03–293–000]**

### Southern Natural Gas Company; Notice of Proposed Changes to FERC Gas Tariff

March 6, 2003.

Take notice that on February 28, 2003, Southern Natural Gas Company (Southern) tendered for filing the following tariff sheets to its FERC Gas Tariff, First Revised Volume No. 2A (Volume 2A):

Effective April 1, 2003.
Cover Sheet.
Second Revised Sheet No. 1.
Second Revised Sheet No. 2.
Second Revised Sheet No. 38.
Effective October 1, 2000.
First Revised Sheet No. 107.

The proposed tariff sheets cancel rate schedules CSS–1, CSS–2 and ST–1 in Volume 2A of Southern's tariff. By order dated January 30, 2003, in Docket No. CP03–21, the Commission authorized the abandonment of the storage services. The storage services associated with these rate schedules were abandoned upon the termination of the primary term of the contracts relating to these services.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6035 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. GT02–35–004]**

### Tennessee Gas Pipeline Company; Notice of Compliance Tariff Filing

March 6, 2003.

Take notice that on February 28, 2003, Tennessee Gas Pipeline Company (Tennessee), Nine Greenway Plaza, Houston, Texas 77046, tendered for filing and acceptance by the Federal Energy Regulatory Commission (Commission) the tariff sheets listed in Appendix A for inclusion in Tennessee's FERC Gas Tariff, Fifth Revised Volume No. 1.

Tennessee states that the revised tariff sheets are being filed in accordance with the Commission's January 29, 2003, order in the referenced proceeding, which relates to Tennessee's previous filings to revise certain of its tariff provisions that primarily deal with the demonstration and maintenance of creditworthiness by Tennessee's customers.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Protest Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6022 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP03–291–000]**

### Viking Gas Transmission Company; Notice of Filing

March 6, 2003.

Take notice that on February 28, 2003, Viking Gas Transmission Company (Viking) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1 the following tariff sheet to become effective April 1, 2003:

Third Revised Sheet No. 5H.
Fourteenth Revised Sheet No. 6B.

The purpose of this filing is to make Viking's annual adjustment to its Load Management Cost Reconciliation Adjustment in accordance with Section 154.403 of the Commission's Rules and Regulations, 18 CFR 154.403, and section 27 of the General Terms and Conditions of Viking's FERC Gas Tariff.

Viking states that copies of the filing have been mailed to all of its jurisdictional customers and to affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6033 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RP03–292–000]**

### Viking Gas Transmission Company; Notice of Filing

March 6, 2003.

Take notice that on February 28, 2003, Viking Gas Transmission Company (Viking) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1 the tariff sheets listed on Appendix A to become effective April 1, 2003.

The purpose of this filing is to make Viking's annual adjustment to its Fuel and Loss Retention Percentages (''FLRP'') in accordance with Section 154.403 of the Commission's Rules and Regulations, 18 CFR 154.403 (2001) and section 26 of the General Terms and Conditions of Viking's FERC Gas Tariff. Application of section 26 of Viking's tariff results in the following new Fuel and Loss Retention Percentages for Rate Schedules FT–A, FT–B, FT–C, FT–D, IT and AOT respectively: 2.37 percent for Zone 1–1, 2.90 percent for Zone 1–2, and .58 percent for Zone 2–2.

Viking states that copies of the filing have been mailed to all of its jurisdictional customers and to affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.314 or 385.211 of the Commission's

Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. 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 proceedings. Any person wishing to become a party must file a motion to intervene. This filing 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 ''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 toll-free at (866) 208–3676, or TTY, contact (202) 502–8659. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link.

*Comment Date:* March 12, 2003.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6034 Filed 3–12–03; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. ER03–171–004, et al.]**

## Entergy Mississippi, Inc., et al.; Electric Rate and Corporate Filings

March 5, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

### 1. Entergy Mississippi, Inc.

[Docket Nos. ER03–171–004 and ER03–589–000]

Take notice that on March 3, 2003, Entergy Services, Inc., on behalf of Entergy Mississippi, Inc., tendered for filing with the Federal Energy Regulatory Commission (Commission), compliance Interconnection Agreement pages addressing the interconnection of South Mississippi Electric Power Association's Silver Creek generating facility, in response to the Commission's January 31, 2003, order in Entergy Mississippi, Inc., 102 FERC ¶61,105.

*Comment Date:* March 24, 2003.

### 2. New England Power Pool

[Docket No. ER03–210–003]

Take notice that on March 3, 2003, ISO New England Inc., submitted a Report of Compliance in response to the January 31, 2003 order issued by the Federal Energy Regulatory Commission in the above-referenced docket.

ISO New England Inc., states that copies of this filing have been served upon NEPOOL Participants and the utility regulatory agencies of the six New England States.

*Comment Date:* March 24, 2003.

### 3. Westar Energy, Inc.

[Docket ER03–578–000]

Take notice that on March 3, 2003, Kansas Gas & Electric Company, Inc. and Westar Energy, Inc. (collectively Westar) submitted for filing a Notice of Cancellation for Rate Schedule FERC Nos. 166, 167, 210, 212 and 246, service agreements between Westar and the City of Iola, Kansas; City of Fredonia, Kansas; City of Waterville, Kansas; City of Scranton, Kansas; and City of Alma, Kansas.

Westar states that copies of this filing were served on the City of Iola, Kansas; City of Fredonia, Kansas; City of Waterville, Kansas; City of Scranton, Kansas; City of Alma, Kansas and the Kansas Corporation Commission.

*Comment Date:* March 24, 2003.

### 4. Northern States Power Company (Minnesota), Northern States Power Company, (Wisconsin)

[Docket No. ER03–579–000]

Take notice that on March 3, 2003 Northern States Power Company (Minnesota), and Northern States Power Company (Wisconsin) jointly tendered for filing revised tariffs sheets to NSP Electric Rate Schedule FERC No. 2, contained in Xcel Energy Operating Companies FERC Electric Tariff, Original Volume Number 3. The revised tariff sheets provide the annual update to Exhibits VII, VIII, and IX of the Restated Agreement to Coordinate Planning and Operations and Interchange Power and Energy between Northern States Power Company (Minnesota) and Northern States Power Company (Wisconsin), accepted for filing in Docket No. ER02–808–000. The NSP Companies request an effective date of January 1, 2003, without suspension.

The NSP Companies state that a copy of the filing has been served upon the State Commissions of Michigan, Minnesota, North Dakota, South Dakota and Wisconsin.

*Comment Date:* March 24, 2003.

### 5. PacifiCorp

[Docket No. ER03–582–000]

Take notice that on March 3, 2003, PacifiCorp tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations, the 2002–03 Operating Procedures under the Pacific Northwest Coordination Agreement.

PacificCorp states that copies of this filing were supplied to the parties to the Pacific Northwest Coordination Agreement.

*Comment Date:* March 24, 2003.

### 6. Entergy Services, Inc., et al.

[Docket No. ER03–583–000]

Take notice that on March 3, 2003, Entergy Services, Inc. (ESI), on behalf of the Entergy Operating Companies, and EWO Marketing LP (EWOM), an affiliated marketer, filed under section 205 of the Federal Power Act for approval of two power purchase agreements between the Entergy Operating Companies and EWOM. ESI and EWOM seek an effective date of April 30, 2003.

ESI states that copies of this filing were served on the affected state utility commissions.

*Comment Date:* March 24, 2003.

### 7. Citizens Communications Company

[Docket No. ER03–584–000]

Take notice that on March 3, 2003, Citizens Communications Company (Citizens) tendered for filing in the above-referenced docket, Rate Schedules 45 and 46 applicable to sales-for-resale service to Mohave Electric Cooperative

*Comment Date:* March 24, 2003.

### 8. Deseret Generation & Transmission Co-operative, Inc.

[Docket No. ER03–585–000]

Take notice that on March 3, 2003 Deseret Generation & Transmission Co-operative, Inc. (Deseret) tendered for filing an amendment to First Revised Service Agreement No. 5 under Deseret's FERC Electric Tariff, Original Volume 1. The amendment includes a second amended and restated Wholesale Power Agreement For Large Industrial Loads (Implementing Deseret Rate Schedule ML–COG1) between Deseret and Moon Lake Electric Association, Inc.

Deseret states that copies of this filing have been served upon Deseret's member cooperatives.

*Comment Date:* March 24, 2003.

**9. New York State Electric & Gas Corporation**

[Docket Nos. ER03–587–000]

Take notice that on March 3, 2003, New York State Electric & Gas Corporation (NYSEG) tendered for filing revisions to its revised retail tariff leaves relating to borderline sales. NYSEG's borderline sales contracts and prior revisions thereto are part of FERC Rate Schedules No. 30, 27, 28, 30, 32, 33, and 105.

NYSEG states that copies of the filing have been served on all parties listed on the New York State Public Service Commission and on the Borderline Utilities.

*Comment Date:* March 24, 2003.

**Standard Paragraph**

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, 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 motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may 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 filed to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. 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 under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6021 Filed 3–12–03; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. EL02–88–002, et al.]**

## Entergy Services, Inc., et al.; Electric Rate and Corporate Filings

March 6, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

**1. Entergy Services, Inc.**

[Docket Nos. EL02–88–002, ER02–1069–004, ER02–1151–004, ER02–1472–004, and ER02–2243–004]

Take notice that on February 28, 2003, Entergy Services, Inc., on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., and Entergy Mississippi, Inc., tendered for filing with the Federal Energy Regulatory Commission (Commission), compliance interconnection and operating agreements with Wrightsville Power Facility, LLC, Plum Point Energy Associates, LLC, Cottonwood Energy Company, LP, Washington Parish Energy Center, LLC, and Reliant Energy Choctaw County, LLC, in response to the Commission's January 28, 2003, and February 26, 2003, order in *Wrightsville Power Facility, L.L.C.,* v. *Entergy Arkansas, Inc., et al.,* 102 FERC ¶ 61,170 and 102 FERC ¶ 61,212.

*Comment Date:* March 21, 2003.

**2. Kinder Morgan Michigan, LLC v. Michigan Electric Transmission Company, LLC**

[Docket No. EL03–12–002]

Take notice that on February 28, 2003, Michigan Electric Transmission Company, LLC (METC) submitted for filing with the Federal Energy Regulatory Commission (Commission) a Generator Interconnection & Operating Agreement with Kinder Morgan Michigan, LLC in compliance with the January 29, 2003, Commission Order in Docket Nos. ER02–1330, *et al.* In addition to submitting the changes directed by the Commission, METC also made ministerial changes to the agreement.

METC states that a copy was served on all parties compiled on the official service list in Docket No. EL03–12, as well as the Michigan Public Service Commission.

*Comment Date:* March 31, 2003.

**3. New England Power Pool**

[Docket No. ER03–210–004]

Take notice that on March 3, 2003, the New England Power Pool (NEPOOL) submitted its Report of Compliance in response to the requirements of the Commission's January 31, 2003, Order in New England Power Pool, 102 FERC ¶ 61,107.

NEPOOL states that copies of these materials were sent to the New England state governors and regulatory commissions and the Participants in NEPOOL.

*Comment Date:* March 24, 2003.

**4. New York Independent System Operator, Inc.**

[Docket No. ER03–238–002]

Take notice that on February 14, 2003, New York Independent System Operator, Inc., (NYISO) submitted for filing an explanation of the non-applicability of day-ahead margin asurance payments to off-dispatch generators under certain conditions, pursuant to the Commission's January 30, 2003, Order in this proceeding.

*Comment Date:* March 17, 2003.

**5. Washington County Power, LLC**

[Docket No. ER03–398–001]

Take notice that on March 4, 2003, Washington County Power, LLC (Washington) tendered for filing an amendment to its market-based rate tariff (MBR Tariff) filed in the above-captioned proceeding. Washington requests that the Federal Energy Regulatory Commission make its MBR Tariff, as amended, effective on March 11, 2003.

*Comment Date:* March 25, 2003.

**6. Klondike Wind Power LLC**

[Docket No. ER03–416–003]

Take notice that on March 3, 2003, Klondike Wind Power LLC amended its January 15, 2003, name change filing with the Federal Energy Regulatory Commission (Commission), which informed the Commission that on December 19, 2002, the name of ''West Valley Generation LLC'' had been changed to ''Klondike Wind Power LLC'' in accordance with 18 CFR 35.16. The amendment reflects the addition of a notice of succession filed under 18 CFR 131.51.

*Comment Date:* March 24, 2003.

**7. PPM Energy, Inc.**

[Docket No. ER03–478–001]

Take notice that on March 3, 2003, PPM Energy, Inc. amended its January 30, 2003, name change filing with the Federal Energy Regulatory Commission (Commission), which informed the Commission that on January 15, 2003, the name of ''PacifiCorp Power Marketing, Inc.'' had been changed to ''PPM Energy, Inc.'' in accordance with

18 CFR 35.16. The amendment reflects the addition of a Notice of Succession filed under 18 CFR 131.51.

*Comment Date:* March 24, 2003.

**8. New England Power Pool**

[Docket No. ER03–586–000]

Take notice that on February 28, 2003, Northeast Utilities Service Company (NUSCO), on behalf of its operating company affiliates, The Connecticut Light and Power Company, Western Massachusetts Electric Company, Holyoke Power and Electric Company and Holyoke Water Power Company (the NU Companies) submitted for filing an amendment (Amendment) to the Settlement Agreement approved by the Commission in Northeast Utilities Service Company, 88 FERC ¶ 61,006 (the Settlement) to extend the rates, terms and conditions of the Settlement for a period of 90 days.

NUSCO states that a copy of this filing has been mailed to the service list.

*Comment Date:* March 11, 2003.

**9. California Independent System Operator Corporation**

[Docket No. ER03–588–000]

Take notice that on March 4, 2003, the California Independent System Operator Corporation (ISO) submitted for Commission filing and acceptance the Utility Distribution Company Operating Agreement (UDC Operating Agreement) between the ISO and the City of Hercules, California. The ISO requests that the UDC Operating Agreement be made effective as of March 1, 2003. The ISO requests privileged treatment, pursuant to 18 CFR 388.112, with regard to portions of the filing.

The ISO states that it has served copies of this filing upon the City of Hercules, California and the California Public Utilities Commission.

*Comment Date:* March 25, 2003.

**10. New England Power Pool**

[Docket No. ER03–590–000]

Take notice that on March 4, 2003, the New England Power Pool (NEPOOL) submitted the Ninety-Fourth Agreement Amending New England Power Pool Agreement, which modifies and clarifies Attachments L, M, N, and O, of the Restated NEPOOL Open Access Transmission Tariff (the NEPOOL Tariff), the Financial Assurance Policy for NEPOOL Members, the Financial Assurance Policy for NEPOOL Non-Participant Transmission Customers, the NEPOOL Billing Policy, and the Financial Assurance Policy for Non-Participants that transact in the Financial Transmission Rights (FTR) Auction and/or Secondary FTR Market, respectively, (collectively, the Policies). NEPOOL states that the changes to the Policies: (i) Reflect NEPOOL's experience with the Policies that were implemented in 2002; (ii) account for certain other financial assurance issues that have arisen since the implementation of the revised Policies; and (iii) make changes to the Policies in connection with the upcoming implementation of Standard Market Design in New England. A May 1, 2003, effective date is requested for these changes.

NEPOOL states that copies of these materials were sent to the NEPOOL Participants, Non-Participant Transmission Customers and the New England state governors and regulatory commissions.

*Comment Date:* March 25, 2003.

**11. PJM Interconnection, L.L.C.**

[Docket No. ES03–26–000]

Take notice that on February 28, 2003, PJM Interconnection, L.L.C. (PJM) submitted an application pursuant to section 204 of the Federal Power Act seeking authorization to issue a long-term, secured note in the amount of $110 million.

PJM also requests a waiver from the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

*Comment Date:* March 27, 2003.

**Standard Paragraph**

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, 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 motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may 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 filed to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. 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 under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6002 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

**[Docket No. EC03–30–000, et al.]**

## Illinois Power Company, et al.; Electric Rate and Corporate Filings

March 7, 2003.

The following filings have been made with the Commission. The filings are listed in ascending order within each docket classification.

**1. Illinois Power Company; Illinois Electric Transmission Company, LLC; Trans-Elect, Inc.**

[Docket Nos. EC03–30–000 and ER03–284–000]

Take notice that on March 4, 2003, Illinois Power Company (Illinois Power), and Illinois Electric Transmission Company, LLC (IETC), Illinois Transco-Holdings, LP (ITH) and Trans-Elect, Inc. (Trans-Elect) (collectively Trans-Elect applicants) (collectively applicants) withdrew that portion of the joint application filed by applicants on December 16, 2002, in which Trans-Elect applicants requested authorization under section 205 of the Federal Power Act for certain rate methodologies and treatments for the provision of open access transmission service over the jurisdictional transmission facilities to be purchased from Illinois Power by IETC.

Applicants state that copies of this filing have been served on all affected state commissions and customers taking service under Illinois Power's open access transmission tariff.

*Comment Date:* March 25, 2003.

**2. NSTAR Electric & Gas Corporation, et al. v. New England Power Pool**

[Docket No. EL03–25–002]

Take notice that on March 3, 2003, the New England Power Pool (NEPOOL) tendered for filing with the Federal Energy Regulatory Commission (Commission) its report of compliance in response to the requirements of the Commission's January 31, 2003, order in

NSTAR Electric & Gas Corporation, *et al.*, 102 FERC ¶61,107 (2003).

NEPOOL states that copies of these materials were sent to the parties to that proceeding, to the NEPOOL participants, non-participant transmission customers and the New England state governors and regulatory commissions.

*Comment Date:* March 31, 2003.

**3. Wolverine Power Supply Cooperative, Inc.**

[Docket No. ES03–27–000]

Take notice that on February 28, 2003, Wolverine Power Supply Cooperative, Inc. (Wolverine) submitted an application pursuant to section 204 of the Federal Power Act seeking authorization to make short-term borrowings under a line of credit with the National Rural Cooperative Finance Corporation in an amount not to exceed $25 million.

Wolverine also requests a waiver from the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

*Comment Date:* March 21, 2003.

**Standard Paragraph**

Any person desiring to intervene or to protest this filing should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, 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 motion to intervene. All such motions or protests should be filed on or before the comment date, and, to the extent applicable, must be served on the applicant and on any other person designated on the official service list. This filing is available for review at the Commission or may 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 toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. 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 under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6006 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

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## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Application Tendered for Filing With the Commission, Soliciting Additional Studies Requests, Establishing Procedural Schedule for Licensing, and a Deadline for Submission of Final Amendments

March 6, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Original Major License, constructed project.

b. *Project No.:* 11810–004.

c. *Date Filed:* January 30, 2003.

d. *Applicant:* City of Augusta.

e. *Name of Project:* Augusta Canal Project.

f. *Location:* Adjacent to the Savannah River, in Richmond County, Georgia, near the town of Augusta, Georgia. The project does not occupy Federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant:* Max Hicks, Director, Utilities Department, 360 Bay Street, Suite 180, Augusta, Georgia 30901, (706) 312–4121.

i. *FERC Contact:* Monte TerHaar, (202) 502–6035 or *monte.terhaar@ferc.gov*.

j. *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 cooperation status should follow the instruction for filing comments described in item l below.

k. 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. Parties who would like to request additional scientific studies should follow the instruction for filing comments described in item l below.

l. Deadline for filing comments on the application: 60 days from date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Additional study requests and requests for cooperating agency status 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 ( *http://www.ferc.gov* ) under the ''e-Filing'' link. After logging into the eFiling system, select ''Comment on Filing'' from the Filing Type Selection screen and continue with the filing process. The Commission strongly encourages electronic filings.

m. This application is not ready for environmental analysis at this time.

n. *The proposed project description:* The City of Augusta does not propose to construct hydroelectric generation facilities and the project would produce no power. Augusta is proposing to license parts of the Augusta Canal system which pass flows for use by three existing hydroelectric projects located in the Augusta Canal. These projects are the 1.2 megawatt (MW) Enterprise Project (No. 2935), the 2.475 MW Sibley Mill Project (No. 5044), and the 2.05 MW King Mill Project (No. 9988). The proposed project would consist of the following: (1) the 1,666-foot-long stone-masonry Augusta Diversion Dam; (2) the 2,250-foot-long Savannah River impoundment between Steven's Creek Dam and the Augusta Diversion Dam; and (3) the first level of the Augusta Canal, which extends about 7 miles between the Augusta Diversion Dam and the Thirteenth Street gates.

o. 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 ''FERRIS'' 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 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

p. With this notice, we are initiating consultation with the Georgia State Historic Preservation Officer as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR, part 800.

q. *Procedural schedule:* At this time we do not anticipate the need for preparing a draft EA. We intend to prepare one, multi-project environmental document which will include the Augusta Canal Project (P–11810), the Enterprise Project (P–2935), and the Sibley Mill Project (P–5044). The EA will include our recommendations for operating procedures and environmental enhancement measures that should be part of any license issued by the Commission. Recipients will have 60 days to provide the Commission with any written comments on the EA. All comments filed with the Commission will be considered in the Order taking final action on the license applications. However, should substantive comments requiring re-analysis be received on the NEPA document, we would consider preparing a subsequent NEPA document.

The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Scoping Document 1—March 2003
Comments on Scoping Document 1—May 2003
Issue acceptance letter/request additional information—May 2003
Additional Information Due—July 2003
Notice of ready for environmental analysis/Notice soliciting final terms and conditions July—2003
Deadline for Agency Recommendations—September 2003
Notice of the availability of the EA—November 2003
Public Comments on EA—due January 2003
Ready for Commission's decision on the application—March 2004

r. 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.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6023 Filed 3–12–03; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Paper Scoping and Soliciting Scoping Comments

March 6, 2003.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* New Minor License.

b. *Project No.:* 1273–009.

c. Date filed: November 15, 2002.

d. *Applicant:* Parowan City.

e. *Name of Project:* Center Creek Hydroelectric Project.

f. *Location:* At the confluence of Center Creek (aka Parowan Creek) and Bowery Creek (a tributary to Parowan Creek) near the City of Parowan, in Iron County, Utah. The project occupies 21.43 acres of land managed by the U.S. Department of the Interior, Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Alden C. Robinson, P.E., Sunrise Engineering, Inc., 25 East 500 North, Fillmore, Utah 84631, (435) 743–6151 and/or Clark Gates II, City Manager, Parowan City, PO Box 576, Parowan, Utah 84761, (435) 477–3331.

i. *FERC Contact:* Gaylord Hoisington, (202) 502–6032, *gaylord.hoisington@ferc.gov*.

j. Deadline for filing scoping comments is April 4, 2003. All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Scoping comments 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, *http://www.ferc.gov* , under the ''e-Filing'' link.

k. This application is not ready for environmental analysis at this time.

l. *Description of the Project:* (1) a 15-foot-high, 54-foot-long concrete overflow type diversion dam; (2) a radial gate; (3) trash racks; (4) a 19.9 acre-foot de-silting pond; (5) an 18 to 26-inch-diameter, 19,300-foot-long steel penstock; (5) a 600-kilowatt powerhouse; and (6) appurtenant facilities.

m. A copy of the application is on file with the Commission and is available for public inspection. This filing is available for review at the Commission or may 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, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (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.

n. Scoping Process—Scoping is intended to advise all parties regarding the proposed scope of the environmental analysis and to seek additional information pertinent to this analysis. The Commission intends to prepare an environmental assessment (EA) for the project in accordance with the National Environmental Policy Act. The EA will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

At this time, the Commission staff do not propose to conduct any formal public or agency meetings or an on-site visit. Instead, we will solicit comments, recommendations, information, and alternatives by conducting paper scoping through issuing Scoping Document 1 (SD1).

Copies of SD1 outlining the subject areas to be addressed in the EA were distributed to the parties on the Commission's mailing list. Copies of SD1 are available for review at the Commission or may 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, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

As part of scoping the staff will: (1) summarize the environmental issues tentatively identified for analysis in the EA; (2) solicit from comments all available information, especially quantifiable data, on the resources at issue; (3) encourage comments from experts and the public on issues that

should be analyzed in the EA, including viewpoints in opposition to, or in support of, the staff's preliminary views; (4) determine the resource issues to be addressed in the EA; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis. Consequently, interested entities are requested to file with the Commission any data and information concerning environmental resources and land uses in the project area and the subject project's impacts to the aforementioned.

o. The tentative schedule for preparing the Center Creek EA is:

Major Milestone—Target Date
Ready for Environmental Analysis Notice—April 23, 2003
Draft EA Issued—July 16, 2003
Final EA Issued—September 17, 2003

**Note:** The schedule is going to vary depending upon the circumstances of the project (deficiencies, additional information, *etc.*) *See* Guidance for Publishing Hydro Licensing Schedules.

**Magalie R. Salas,**
*Secretary.*
[FR Doc. 03–6024 Filed 3–12–03; 8:45 am]
**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## Notice of Application Tendered for Filing With the Commission, Establishing Procedural Schedule for Relicensing, and a Deadline for Submission of Final Amendments

March 6, 2003.

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.:* 2169–020.

c. *Date Filed:* February 21, 2003.

d. *Applicant:* Alcoa Power Generating Inc (APGI).

e. *Name of Project:* Tapoco Project.

f. *Location:* On the Little Tennessee and Cheoah Rivers in Graham and Swain Counties, North Carolina and Blount and Monroe Counties, Tennessee. The project affects Federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Norman L. Pierson, Property and Relicensing Manager, Alcoa Power Generation Inc., Tapoco Division, 300 North Hall Road, Alcoa, TN 37701–2516, (865) 977.3326.

i. *FERC Contact:* Randy Yates at (770) 452–3778, or *lorance.yates@ferc.gov*.

j. *Deadline for filing comments on the application:* 60 days from the filing date.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

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 cooperation status should follow the instruction for filing comments described in the item j above. 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.

l. This application is not ready for environmental analysis at this time.

m. *The proposed Tapoco Project includes four developments:* Santeetlah Development consisting of: (1)1,054-foot-high and 216-foot-high concrete arch dam; (2) 25,176 foot long tunnel/pipeline; (3) 2,881-acre reservoir; (4) powerhouse with two generating units, with the total installed capacity of 49.2 MW; and (5) 750-foot-long 161 kV transmission line.

Cheoah Development consisting of: (1) 750-foot-long and 229-foot high curved concrete gravity dam; (2) 644-acre reservoir; (3) powerhouse with 4 vertical Francis turbine units directly connected to generators and 1-independent Francis turbine unit added in 1949; and (4) 118-MW total installed capacity.

Calderwood Development consisting of: (1) 916-foot-long and 230-foot-high concrete arch dam; (2) 570-acre reservoir; (3) 2,050-foot-long tunnel; and (4) powerhouse with 3 Francis turbine units, which are being upgraded to a total installed capacity of 140.4 MW.

Chilhowee Development consisting of: (1) 1,483-foot-long and 88.5-foot-high concrete gravity dam; (2) 1.734-acre reservoir; and (3) powerhouse with 3 Kaplan turbine units with a total installed capacity of 52.2 MW

APGI is planning a refurbishment/upgrade at several of the units during the term of the new license and proposes to modify project operations in connection with the environmental measures described in the application.

n. 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 ''FERRIS'' 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 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

o. Procedural schedule and final amendments: At this time we anticipate a comprehensive settlement to be submitted to the Commission and therefore we do not anticipate the need for preparing a draft EA. We intend to prepare a single environmental document. The EA will include our recommendations for operating procedures and environmental enhancement measures that should be part of any license issued by the Commission. Recipients will have 60 days to provide the Commission with any written comments on the EA. All comments filed with the Commission will be considered in the Order taking final action on the license applications. However, should substantive comments requiring reanalysis be received on the NEPA document, we would consider preparing a subsequent NEPA document.

The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule may be made as appropriate.

Issue Acceptance letter—May 2003.

Notice soliciting final terms and conditions—May 2003.

Deadline for Agency Recommendations—July 2003.

Notice of the availability of the EA—November 2003.

Public Comments on EA due—January 2004.

Ready for Commission's decision on the application—July 2004.

Final amendments to the application must be filed with the Commission no later than 45 days from the issuance date of the notice soliciting final terms and conditions.

p. With this notice, we are initiating consultation with the Tennessee and North Carolina State Historic Preservation Officers as required by § 106, National Historic Preservation Act, and the regulations of the Advisory

Council on Historic Preservation, 36 CFR, part 800.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6025 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Notice of Application Tendered for Filing With the Commission, Soliciting Additional Study Requests, and Establishing Procedures for Relicensing and a Deadline for Submission of Final Amendments

March 6, 2003.

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.:* 382–026.

c. *Date Filed:* February 26, 2003.

d. *Applicant:* Southern California Edison Company.

e. *Name of Project:* Borel Hydroelectric Project.

f. *Location:* On the Kern River near the town of Bodfish in kern County, California.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Nino J. Mascolo, Senior Attorney, Southern California Edison Co., 2244 Walnut Grove Avenue, PO Box 800, Rosemead, California 91770; (626) 302–4459.

i. *FERC Contact:* Kenneth Hogan at (202) 502–8434 or *kenneth.hogan@ferc.gov*.

j. *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 instructions for filing comments described in item k below.

k. Deadline for filing additional study requests is 60 days from the date of this notice.

All documents (original and eight copies) should be filed with: Ms. Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Additional study requests 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 (*http://www.ferc.gov*) under the ''e-Filing'' link. After logging into the e-Filing system, selecte ''Comment on Filing'' from the Filing Type Selection screen and continue with the filing process.

l. This application is not ready for environmental analysis at this time.

m. The existing Borel Hydroelectric Project (Project) consists of: (1) 158-foot long, 4-foot-high concrete diversion dam with fishway; (2) a 61-foot-long intake structure with three 10-by 10-foot radial gates; (3) a canal inlet structure consisting of a canal intake, trash racks, and a sluice gate; (4) a flowline with a combined total length of 1,985-feet of tunnel, 1,651-feet of steel Lennon flume, 3,683-feet of steel siphon, and 51,835-feet of concrete-lined canal; (5) four steel penstock, penstocks 1 and 2 are 526-feet-long and 565-feet-long, respectively with varying diameters between 42 and 60 inches, penstocks 3 and 4 each have a 60-inch-diameter and extend 622-feet at which point they wye together to form a single 84-inch-diameter, 94-foot-long penstock; (6) a powerhouse with two 3,000 kW generators and a 6,000kW generator for a total installed capacity of 12,000 kW or 12 MW; and (7) other appurtenant facilities. The Project has no storage capability and relies on water releases from Lake Isabella made by the U.S. Army Corp of Engineers.

n. A copy of the application is on file with the Commission and is available for public inspection. 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 filed to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (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.

o. With this notice, we are initiating consultation with the California 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 800.4.

p. Procedural schedule and final amendments: The application will be processed according to the following milestones, some of which may be combined to expedite processing:

Issue Deficiency Letter—May, 2003.
Notice of application accepted for filing—July, 2003.
Issuance of NEPA Scoping Document 1, for comments—August, 2003.
Request for Additional Information—September, 2003.
Issuance of NEPA Scoping Document 2—October, 2003.
Notice of application is ready for environmental analysis—November, 2003.
Notice of the availability of the draft NEPA document—April, 2004.
Notice of the availability of the final NEPA document—September, 2004.
Order issuing the Commission's decision on the application—October, 2004.

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.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6028 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. RM98–1–000]**

### Regulations Governing Off-the-Record Communications; Public Notice

March 7, 2003.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any

responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires.

Any person identified below as having made a prohibited off-the-record communication should serve the document on all parties listed on the official service list for the applicable proceeding in accordance with rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

[Docket No. RM98–1–000]The following is a list of exempt and prohibited off-the-record communications recently received in the Office of the Secretary. These filings are 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 ''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 toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

| Docket No. | Date filed | Presenter or requester |
|---|---|---|
| **Prohibited** | | |
| 1. Project No. 2342–000 | 2–20–03 | Anita Gale. |
| 2. Project No. 2342–000 | 3–5–03 | Kya Eckstrand. |
| **Exempt** | | |
| 1. RP00–241–000 | 2–19–03 | Brenda L. Mackall. |
| 2. CP02–396–000 | 2–25–03 | Steven A. Minnich. |
| 3. Project No. 6032–000 | 2–25–03 | Deborah Osborne. |
| 4. Project No. 2042–013 | 2–27–03 | William Ryan. |
| 5. Project No. 184–000 | 3–3–03 | Frank Winchell. |
| 6. Project No. 2042–013 | 3–3–03 | Gordon Macatee. |
| 7. Project No. 2086–000 | 3–04–02 | Lorrie Planas. |

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6004 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 11854–002]**

### Ketchikan Public Utilities; Notice of Surrender of Preliminary Permit

March 7, 2003.

Take notice that Ketchikan Public Utilities, permittee for the proposed Connell Lake Project, has requested that its preliminary permit be terminated. The permit was issued on July 3, 2001, and would have expired on June 30, 2004. The project would have been located on Connell Lake and Ward Creek in Ketchikan Gateway Borough, Alaska.

The permittee filed the request on January 29, 2003, and the preliminary permit for Project No. 11854 shall remain in effect through the 30th day after issuance of this notice unless that day is a Saturday, Sunday, or holiday as described in 18 CFR 385.2007, in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR part 4, may be filed on the next business day.

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 03–6003 Filed 3–12–03; 8:45 am]

BILLING CODE 6717–01–P

## ENVIRONMENTAL PROTECTION AGENCY

**[OAR–2002–0092; FRL–7466–1]**

### Agency Information Collection Activities; Submission of EPA ICR No. 1772.03, OMB Control No. 2060–0347 to OMB for Review and Approval; Comment Request

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: Activities Associated with EPA's Energy Star Program in the Commercial and Industrial Sectors. This ICR describes the nature of the information collection and its estimated burden and cost.

**DATES:** Additional comments may be submitted on or before April 14, 2003.

**ADDRESSES:** Follow the detailed instructions in **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Mary Susan Bailey, Climate Protection Partnerships Division, Mailcode: 6202J, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–0189; fax number: (202) 565–2083; e-mail address: *bailey.marysusan@epa.gov.*

**SUPPLEMENTARY INFORMATION:** EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 29, 2002 (67 FR 65979), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. OAR–2002–0092, which is available for public viewing at the Air and Radiation Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice, and according to the following detailed instructions: (1) Submit your comments to EPA online using EDOCKET (our preferred method), by e-mail to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) Mail your comments to OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

*Title:* Activities Associated with EPA's Energy Star Program in the Commercial and Industrial Sectors, (OMB Control No. 2060–0347, EPA ICR No. 1772.03). This is a request to renew an existing approved collection that is scheduled to expire on April 30, 2003. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

*Abstract:* Energy Star is a voluntary program to encourage organizations to prevent pollution rather than controlling it after its creation. The Program focuses on reducing utility-generated emissions by reducing the demand for energy. In 1991, EPA launched the Green Lights program to encourage corporations, State and local governments, colleges and universities, and other organizations to adopt energy-efficient lighting as a profitable means of preventing pollution and improving lighting quality. Since then, EPA has rolled Green Lights into Energy Star and expanded Energy Star to encompass organization-wide energy performance improvement, such as building technology upgrades, product purchasing initiatives, and employee training. At the same time, EPA has streamlined the reporting requirements of Energy Star and focused on providing incentives for improvements (*e.g.*, Energy Star Awards Program). EPA also makes tools and other resources available over the Web to help the public overcome the barriers to evaluating their energy performance and investing in profitable improvements.

To join Energy Star, organizations are asked to complete a Partnership Letter or Agreement that establishes their commitment to energy efficiency. Partners agree to undertake efforts such as measuring, tracking, and benchmarking their organization's energy performance by using tools such as those offered by Energy Star; developing and implementing a plan to improve energy performance in their facilities and operations by adopting a strategy provided by Energy Star; and educating staff and the public about their Partnership with Energy Star, and highlighting achievements with the Energy Star Label, where available.

Partners also may be asked to periodically submit information to EPA as needed to assist in program implementation. For example, EPA compiles the Energy Service and Product Provider Directory to provide the public with easy access to energy efficiency products and services. Businesses wishing to appear in this directory are asked to submit a completed form that details their products and services.

Partnership in Energy Star is voluntary and can be terminated by Partners or EPA at any time. EPA does not expect organizations to join the program unless they expect participation to be cost-effective and otherwise beneficial for them.

In addition, Partners and any other interested party can help EPA promote energy-efficient technologies by evaluating the efficiency of their buildings by benchmarking individual buildings by using EPA's on-line benchmarking tool, Portfolio Manager, and apply for Energy Star Labels if their performance ranks in the top 25 percent. If they can demonstrate that an individual building meets the Energy Star criteria, they will receive an Energy Star plaque that they can display on the building. EPA does not expect to deem any information collected under Energy Star to be Confidential Business Information (CBI).

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, and are identified on the form and/or instrument, if applicable.

*Burden Statement:* The annual public reporting and recordkeeping burden for this collection of information will vary depending on the type of participant, the specific collection activity, and other factors. The annual burden for joining Energy Star and conducting related activities is estimated to range from about 2 to 8 hours per respondent. This includes time for preparing and submitting the Partnership Letter or Agreement and other information as requested. The burden for applying for an Energy Star Label is estimated to range from about 5.5 to 10.5 hours per respondent. This includes time for reading the instructions of the benchmarking tool if needed, gathering and entering information on building characteristics and energy use into the tool, printing a score report, and preparing/submitting the Energy Star Label application materials to EPA. The burden for applying for an Energy Star Award is estimated to range from 4 to 26.5 hours per respondent. This includes time for preparing and submitting the awards application materials to EPA.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the

existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

*Respondents/Affected Entities:* Participants in EPA's Energy Star Program in the Commercial and Industrial Sectors.

*Estimated Number of Respondents:* 5,000.

*Frequency of Response:* One-time, annually, and/or periodically, depending on type of respondent and collection.

*Estimated Total Annual Hour Burden:* 83,343 hours.

*Estimated Total Annual Cost:* $6,594,941, including $1,540,530 in annualized capital or O&M costs.

*Changes in the Estimates:* There is a decrease of 134,371 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is a result of EPA's streamlining of Energy Star's information collections since preparing ICR 1772.02. EPA now places a greater emphasis on providing voluntary incentives for improvements and has simplified its collections. For example, EPA no longer requires Partners to submit the Annual Facility Report (AFR), which took Partners over 198,000 hours to prepare/submit annually. EPA also simplified other paperwork related to their Partnership. Organizations had previously submitted a Memorandum of Understanding (MOU) to join the program, which took about five hours to complete. Partners now prepare a more streamlined Partnership Letter or Agreement, which takes between 2 and 2.5 hours. EPA estimates that its streamlining has resulted in 203,743 hours in burden reduction annually.

This burden reduction is partially offset, however, because EPA also expects to see greater benchmarking activity over the coming years. EPA developed a Web-based tool, Portfolio Manager, to help organizations benchmark the energy use in their buildings. ICR 1772.02 estimated about 2,300 benchmarkings per year, whereas ICR 1772.03 estimates more than 23,000 benchmarkings per year. This expected growth reflects EPA's view that an increased number of organizations will find Portfolio Manager beneficial and use it to improve their energy performance. EPA also expects to conduct activities to expand and refine Portfolio Manager (*e.g.*, information collection and beta testing to expand Portfolio Manager to include new space use types). EPA expects to see an annual burden increase in benchmarking and related activities of 69,372 hours.

In summary, EPA estimates that the burden reduction of 203,743 hours explained above will be partially offset by the burden increase of 69,372 hours resulting from increased benchmarking and related activities. The result is a net burden reduction of 134,371 hours annually.

Dated: February 25, 2003.

**Oscar Morales,**

*Director, Collection Strategies Division.*

[FR Doc. 03–6108 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

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## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7466–3]**

## Office of Air and Radiation Environmental Internship Assistance Competition: Solicitation Notice

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice; request for initial proposals.

**SUMMARY:** This document solicits proposals from educational institutions and nonprofit organizations to provide internships for undergraduate students with internships in various environmental positions at EPA, Native American Tribal lands, and other institutions. Students are provided with work experience that will enable them to prepare to become future leaders in the environmental field. Additionally, the internship will provide a consciousness that will enable the student to recognize and manage complex environmental problems.

**SUPPLEMENTARY INFORMATION:**

**Contents by Section**

I. Background/ Purpose
II. Funding Issues
III. Eligibility
IV. Cooperative Agreement
V. Deadlines/ Dates
VI. Program Design
VII. Criteria/ Scope
VIII. Proposals Format
IX. Where and When to Submit
X. Pre-application Assistance
XI. Notification of Proposal Receipt
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XIII. Completed Application Package
XIV. Executive Order 12372
XV. Award Date
XVI. Dispute Resolution Process
XVII. Applicable Regulations
XVIII. Confidential Business Information

### I. Background/ Purpose

This document solicits cooperative agreement proposals from educational institutions and non-profit organizations supporting the Office of Air and Radiation's Environmental Internship Program. This cooperative agreement will provide summer internships for undergraduate students with internships in various environmental positions at EPA, Native American Tribal lands, and other institutions. EPA will provide students with work experience and orientation to support their environmental training positions. This assistance agreement will enable students to prepare to become future leaders in the environmental field and to recognize and appropriately manage complex environmental problems. It will also provide students with an environmental consciousness to encourage them to pursue environmental careers and become environmentally conscious citizens. Because this internship involves possible placement of interns onto Tribal lands, special consideration will be given to schools that have had a demonstrated history of recruiting students with prior experience working on tribal issues. However, all universities are encouraged to apply. The Catalogue of Federal Domestic Assistance (CFDA) for this program is 66.607.

### II. Funding Issues

Depending upon the availability of funds, it is anticipated that a total of approximately $400,000 over three years, including direct and indirect costs, will be awarded in FY 2003. Proposals may request funding with a total project cost of up to $133,333 per year with a duration of up to three years. This cooperative agreement is authorized under CAA section 103(b)(3) and no matching funds are required from the recipient.

### III. Eligibility

Organizations being targeted for this assistance agreement include accredited 4-year educational institutions and non-profit organizations. EPA reserves the right to reject all applications and make no awards.

### IV. Cooperative Agreement

The resulting award will be a Cooperative Agreement. Cooperative Agreements involve substantial involvement between the EPA Project Officer and the selected applicant. Anticipated substantial Federal involvement for this project will include:

1. The EPA Project Officer will be part of the final evaluation of the interns for placement. The final decision of intern

selection and placement rests with the recipient.

2. No stipend dollars will be used for any other purposes without the prior approval of the EPA Project Officer.

3. The EPA Project Officer will accompany the recipient on site visits (internship placement locations) and recruitments, when necessary.

**V. Deadlines/Dates**

In order to efficiently manage the selection process, the Office of Air and Radiation requests that an informal ''Intent to Apply'' be submitted by March 28, 2003. (Please provide project title or subject and e-mail address.) An ''Intent to Apply'' simply states, in the form of e-mail, mail, or fax, that your organization intends to submit a proposal to be received by the deadline. Submitting an ''Intent to Apply'' does not commit an organization to submit a pre-proposal. The ''Intent to Apply'' is an optional submission; those not submitting an ''Intent to Apply'' may still apply by the deadline for submitting proposals, which is April 29, 2003. However, only those submitting an intent to apply will be given the conference call-in number for pre-application assistance (please see section X ''Pre-application assistance''). Instructions for submitting Intents to Apply and Proposals are found in section IX ''Where and When to Submit.''

**VI. Program Design**

EPA anticipates student stipends to be approximately $4,500 per semester and the housing allowance to be approximately $1,500 (on an as-needed basis.) The Office of Air and Radiation expects to host a minimum of ten students per semester. Applicants should describe the following in detail:

• *Recruitment:* Each proposal should address their recruitment process in terms of obtaining a diverse population of students. Universities that have a demonstrated history of recruiting students who have had prior experience on tribal issues will be given special consideration.

• *Stipends:* Ability to process student stipends. Describe process for paying student stipends.

• *Tracking:* Ability to track students after completing the environmental program (*i.e.* final employment selections, location of position, post-graduate work) for the purposes of creating an alumni database, measure effectiveness of program and to provide new students with information and phone numbers of previous students.

• *Student Application Processing and Evaluation:* Recipients must have a system to process and evaluate applications. At a minimum, the application process must evaluate potential interns on the basis of their academic record, computer skills, awards, and writing skills. Special consideration will be given to applicants that have scholarships, fellowships and/or work experience on tribal issues. Students must have a grade point average of 2.8 or higher to meet eligibility for internships at EPA.

• *Eligibility requirements for internships:* Students must be enrolled in a four-year accredited college or university. Students enrolled in a four-year college or university must have achieved at least second semester sophomore standing, or have completed 45 credit hours of academic study.

• *Internship Management:* Their recruitment priorities, internship management and how they foresee interaction with EPA. Applicants should describe training for students (i.e. environmental, math, science courses), and student intern performance evaluations.

• *Orientation in Washington, DC:* The orientation program should provide an opportunity for students to familiarize themselves with their prospective program offices and the functions of the program office as well as the issues of the specific media (water, air, solid waste, etc).

• *Placements:* Applicants should describe the process and how they will select placement sites focusing on tribal placements, when applicable.

• *Housing:* Include how housing (if needed) will be provided to students in the various project sites.

• *Personnel and Administrative Services:* Include how personnel and administrative services for interns will be provided. Such services should include ensuring students provide their own short-term sickness and accident insurance and assisting students with financial support (bank services for student to deposit stipend checks, etc.).

• *Program Effectiveness:* How the applicant plans to evaluate the success of each year of the three-year program, and what corrective action they will take to make any necessary improvements.

**VII. Criteria/Scope**

• *Review and Selection Process:* Proposals submitted to EPA headquarters will be evaluated using the criteria defined below. Proposals will be reviewed in two phases—the screening phase and the evaluation phase. During the screening phase, proposals will be reviewed to determine whether they meet the eligibility requirement of this document (please see section III ''Eligibility''). Only those proposals that meet the eligibility requirement will enter the full evaluation phase of the review process. During the evaluation phase, proposals will be evaluated based upon the quality of their proposals. Reviewers conducting the screening and evaluation phases of the review process will include EPA officials and external environmental educators approved by EPA. At the conclusion of the evaluation phase, the reviewers will score work plans, on a one hundred point scale, based upon the system below:

| Criterion | Maximum points per criterion |
|---|---|
| Effectiveness of overall work plan and ability to cover all items listed in Section VI ''Program Design'' | 25 |
| Ability to recruit a diverse group of students and those with prior experience working on tribal issues or having familiarity and knowledge about tribal issues | 20 |
| Effectiveness of placements focusing on site and diversity of placement | 20 |
| Ability to plan and execute an orientation for each internship class | 20 |
| Ability to evaluate student performance | 10 |
| A detailed yearly budget | 5 |
| Total Points Possible | 100 |

• After the scores are evaluated and ranked, the selected applicant will be asked to submit a complete application package. For further information on submitting completed application packages, please see Section XIII below.

**VIII. Proposal Format**

The proposal should conform to the following outline:

1. Title

2. Applicant (Organization) and contact name, phone number, fax and e-mail address

3. Summary of funds requested

4. Project period: Beginning and ending dates (for planning purposes, applicants should assume funds will be available on August 1, 2003).

5. Project work plan (including a description of all tasks, dates of completion, products and deliverables). The project work plan should cover all items listed in section VI ''Project Design.''

6. Report Schedule: Acknowledgment of quarterly report requirement (schedule established by EPA) and planned final report submission date (due 90 days after the project end date).

7. Budget (Please provide with a narrative explanation for the following categories):

a. Personnel.
b. Fringe Benefits.
c. Contractual Costs.
d. Travel.
e. Equipment.
f. Supplies.
g. Other.
h. Total Direct Costs (add a–g).
i. Total Indirect Costs (must include documentation of accepted indirect rate).
j. Total Cost (add h and i).

Costs proposed in the budget must be linked directly to the proposal. For example, if there is travel in connection with recruiting efforts, the budget should reflect travel costs.

8. Attach a one page resume for key personnel conducting the project.

**IX. Where and When To Submit**

Please submit intents to apply by March 28, 2003 Intents to Apply must be e-mailed, faxed, or mailed to the Project Officer, Linda Zarow. If Intents to Apply are mailed, they must be received by March 28, 2003. Only those submitting an ''Intent to Apply'' will be given the conference call-in number for pre-application assistance (please see section X ''Pre-application Assistance''). Send ''Intents to Apply'' to: Linda Zarow, Ariel Rios Building, 1200 Pennsylvania Ave., Washington, DC 20004; mail code 6101A; Rm 5433; fax: (202) 501–1004; email: *zarow.linda@epa.gov*. Please include organization name, contact, and phone number.

Please submit proposals by April 29, 2003 (Remember, the Intent to Apply is not required and will have no bearing on the judging process, we recommend it for the benefit of our planning process only.) Please submit an original and three copies of the proposal. Submission of the Intent to Apply does not commit the applicant to submit a proposal. Submission of an Intent to Apply or a proposal does not guarantee funding. Electronic proposals will be accepted.

**X. Pre-Application Assistance**

To ensure that every interested party has equal opportunity to gain any needed additional administrative information useful to the application process, the Office of Air and Radiation has scheduled one conference call. The call will take place on April 10, 2003 from 10 AM to 12 PM EST. A call-in number will provided to those who submit an Intent to Apply. Questions and answers from this conference call will be summarized and posted on OAR's web-site. The web-site address will be available at the pre-application assistance conference. Federal rules protecting applicants' equal access to information prohibit any other contact that would result in information given to some but not all applicants. Therefore, as much as it desires to encourage all interested applicants, EPA can give no other assistance prior to final submission of applications. Requests for information outside the context of this conference call cannot be answered. The content of the call is entirely dependent upon questions asked.

**XI. Notification of Proposal Receipt**

If the applicant includes a stamped, self-addressed postcard along with proposal, the applicant will be notified of proposal receipt.

**XII. Notification of Unsuccessful Offerors**

The Office of Air and Radiation will notify all unsuccessful offerors no later than 60 days after notifying the selected applicant.

**XIII. Completed Application Packages**

*Completed application package:* Applies only to the selected applicant. The selected applicant will be contacted by the Project Officer and will be requested to submit a complete application. Instruction on how to obtain an application tool kit will be provided at that time. The application must be postmarked or received by regular or express mail on or before midnight May 30, 2003. Please provide an original and six copies. Electronic applications will be accepted.

The application package should be submitted to Linda Zarow at: Ariel Rios Building, 1200 Pennsylvania Ave. Rm. 5433, Washington DC 20004; mail code 6101A. Courier or personally delivered applications must be brought to the same address.

**XIV. Executive Order 12372**

The applicant selected for funding will be required to provide a copy of the proposal to their designated State Point of Contact for review, pursuant with Executive Order 12372. This review is not required of initial proposals; only to the selected applicant.

**XV. Award Date**

Subject to the availability of funding, awards should be made by August 1, 2003 for placement in the summer term 2004.

**XVI. Dispute Resolution Process**

The Agency will resolve any disputes arising from this solicitation pursuant to the procedures outlined at 40 CFR 30.63 and § 31.70, subpart F.

**XVII. Applicable Regulations and OMB Circulars**

The applicant selected will abide by 40 CFR part 30, OMB Circular A–122, and OMB Circular A–133.

**XVIII. Confidential Business Information**

If any portion of an applicant's proposal is comprised of confidential business information (CBI), appropriate pages should be so marked at the top of each page.

**FOR FURTHER INFORMATION CONTACT:** Linda Zarow, USEPA, Office of Air and Radiation, Immediate Office, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20004, Mail Code 6101A, Rm 5433. Telephone (202)564–7431; Fax (202) 501–1004; or e-mail: *zarow.linda@epa.gov*.

Dated: March 7, 2003.

**Elizabeth Craig,**

*Deputy Assistant Administrator, Office of Air and Radiation.*

[FR Doc. 03–6107 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2002–0353; FRL–7286–3]**

## Experimental Use Permit; Receipt of Applications

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of applications 68467–EUP–3, 68467–EUP–5, 68467–EUP–T, 68467–EUP–I, 29964–EUP–1, 29964–EUP–3, 29964–EUP–U, and 29964–EUP–L from Mycogen Seeds/Dow Agrosciences LLC and Pioneer Hi-Bred International requesting experimental use permits (EUPs) and EUP amendments for 1) *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 14352) in corn, 2) *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 12560) in corn, 3) *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 17662) in corn, and 4) *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 17658) in corn.

The Agency has determined that the applications may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on these applications.

**DATES:** Comments, identified by docket ID number OPP–2002–0353, must be received on or before April 14, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: mendelsohn.mike@epa.gov.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest to those persons who are interested in agricultural biotechnology or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

### *B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0353. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

### *C. How and To Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and

follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2002–0353. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2002–0353. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency (7502C), 1200 Pennsylvania Ave., NW., Washington, DC, 20460–0001, Attention: Docket ID Number OPP–2002–0353.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2002–0353. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

*D. How Should I Submit CBI To the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the notice.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Background

Both Mycogen Seeds/Dow AgroSciences LLC and Pioneer Hi-Bred International have applied to amend EUPs 68467–EUP–3, 68467–EUP– 5, 29964–EUP–1, and 29964–EUP–3 for *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 14352) in corn and *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 12560) in corn to allow plant material grown under these EUPs to be used for food and/or feed. The original notice of approval for these EUPs published in the **Federal Register** on February 20, 2002 (67 FR 7688) (FRL–6820–3). Under the original notice, the Cry34/35Ab1 proteins were described as 149B1 protein since they had not yet received their *Bacillus thuringiensis* Pesticidal Crystal Proteins Nomenclature designation, http://www.biols.susx.ac.uk/home/Neil_Crickmore/Bt/. These proteins have now been designated as Cry34Ab1 and Cry35Ab1 by the *Bacillus thuringiensis* Pesticidal Crystal Proteins Nomenclature Committee, a non-governmental scientific committee.

Mycogen Seeds/Dow AgroSciences LLC and Pioneer Hi-Bred International have also applied for EUPs involving *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 17662) in corn, and *Bacillus thuringiensis* Cry34/35Ab1 protein and the genetic material necessary for its production (from the insert of plasmid PHP 17658) in corn. These EUPs have been proposed as non-crop destruct.

For Mycogen Seeds/Dow AgroSciences LLC, 394 acres each are proposed under 68467–EUP–I and 68467–EUP–T for testing in Colorado, Hawaii, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Puerto Rico, South Dakota, Texas, and Wisconsin. Testing is to include maize breeding and observation nursery, maize agronomic observation, herbicide tolerance, maize efficacy, insect resistance management, and maize demonstration trials.

For Pioneer Hi-Bred International, 623 acres are proposed under 29964–EUP–U and 624 acres are proposed under 29964–EUP–L for testing in California, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, and Wisconsin. Testing is to include insect resistance management, maize agronomic observation, maize breeding and observation nursery, maize demonstration, maize efficacy, maize hybrid production plots, maize regulatory field studies, non-target organism, and herbicide tolerance trials.

## III. What Action is the Agency Taking?

Following the review of the Mycogen Seeds/Dow Agrosciences LLC and Pioneer Hi-Bred International's applications and any comments and data received in response to this notice, EPA will decide whether to issue or deny these EUP requests. Any issuance of EUPs will be announced in the **Federal Register**.

**IV. What is the Agency's Authority for Taking This Action?**

The specific legal authority for EPA to take this action is under FIFRA section 5.

**List of Subjects**

Environmental protection, Experimental use permits.

Dated: March 5, 2003.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

[FR Doc. 03–6187 Filed 3–11–03; 2:49 pm]

BILLING CODE 6560–50–S

## EXPORT-IMPORT BANK OF THE UNITED STATES

### Notice of Open Special Meeting of the Advisory Committee of the Export-Import Bank of the United States (Ex-Im Bank).

**SUMMARY:** The Advisory Committee was established by Public Law 98–181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank of the United States to Congress.

*Time and Place:* Monday, March 24, 2002, at 9:30 a.m. to 12:30 p.m. The meeting will be held at Ex-Im Bank in Room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

*Agenda:* Agenda items include an introduction of Advisory Committee responsibilities, a legislative update, introduction of topics for the year, and discussion of the Advisory Committee's recommendations to Ex-Im Bank.

*Public Participation:* The meeting will be open to public participation, and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to March 17, 2003, Michele Kuester, Room 1243, 811 Vermont Avenue, NW., Washington, DC 20571, Voice: (202) 565–3766 or TDD (202) 565–3377.

**FOR FURTHER INFORMATION CONTACT:** Michele Kuester, Room 1243, 811 Vermont Ave., NW., Washington, DC 20571, (202) 565–3766.

**Peter Saba,**

*General Counsel.*

[FR Doc. 03–6054 Filed 3–12–03; 8:45 am]

BILLING CODE 6690–01–M

## FEDERAL ELECTION COMMISSION

### Sunshine Act; Notice of Meeting

* * * * *

*Previously Announced Date and Time:* Thursday, February 27, 2003, meeting open to the public. This meeting was cancelled.

* * * * *

*Previously Announced Date and Time:* Thursday, March 6, 2003: The following item has been added to the agenda: Administrative fines—final rules and explanation and justification.

* * * * *

*Previously Announced Date and Time:* Friday, March 14, 2003, meeting open to the public. This meeting was cancelled.

* * * * *

*Date and Time:* Tuesday, March 18, 2003, at 10 a.m.

*Place:* 999 E Street, NW., Washington, DC.

*Status:* This meeting will be closed to the public.

*Items to be Discussed:* Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

*Date and Time:* Thursday, March 20, 2003, 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.

Notice of proposed rulemaking on public funding of Presidential primary and general election candidates and conventions.

Administrative matters.

*Person to Contact for Information:* Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

**Mary W. Dove,**

*Secretary of the Commission.*

[FR Doc. 03–6175 Filed 3–11–03; 2:36 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 # | Acquiring | Acquired | Entities |
|---|---|---|---|
| **Transactions Granted Early Termination—12/30/2002** | | | |
| 20030207 | Albert G. Lowenthal | Canadian Imperial Bank of Commerce. | Canadian Imperial Bank of Commerce. |
| 20030212 | General Motors Corporation | DaimlerChrysler AG | New Venture Gear of Indiana, LLC. |
| 20030215 | The Dun & Bradstreet Corporation. | Hoover's, Inc | Hoover's, Inc. |
| 20030225 | Blackstone Capital Partners IV Merchant Banking Fund L.P. | Northrop Grumman Corporation | Automotive Holdings Corp. |
| 20030230 | Barry Diller | Entertainment Publications, Inc | Entertainment Publications, Inc. |
| 20030231 | AmerisourceBergen Corporation | Whitney V, L.P | US Bioservices Corporation. |
| 20030233 | MDU Resources Group, Inc | PG&E Corporation | Mountain View Power Partners, LLC. |

| Trans # | Acquiring | Acquired | Entities |
|---|---|---|---|
| 20030234 | David H. Murdock | Dole Food Company, Inc | Dole Food Company, Inc. |
| **Transactions Granted Early Termination—01/02/2003** | | | |
| 20030239 | Sumitomo Corporation | Marubeni Corporation | Mitchell Distributing Company LLC. |
| 20030240 | Kerry Group plc | A.M. Todd Group, Inc | SurPure, Ltd. |
| 20030243 | Kerry Group plc | Hadi B. Lashkajani | SunPure, Ltd. |
| **Transactions Granted Early Termination—01/06/2003** | | | |
| 20030221 | Friedman, Billings, Ramsey Group, Inc. | FBR Asset Investment Corporation. | FBR Asset Investment Corporation. |
| 20030222 | FBR Asset Investment Corporation. | Friedman, Billings, Ramsey Group, Inc. | Friedman, Billings, Ramsey Group, Inc. |
| **Transactions Granted Early Termination—01/07/2003** | | | |
| 20030227 | UCB S.A | Solutia Inc | Solutia Inc. |
| 20030238 | Groupe Danone | Stonyfield Farm, Inc | Stonyfield Farm, Inc. |
| 20030248 | Phillips-Van Heusen Corporation | Calvin Klein, Inc | Calvin Klein, Inc. |
| 20030250 | ALLTEL Corporation | N. Eric Jorgensen | Cellular XL Associates, L.P. |
| 20030251 | Apax Excelsior VI, L.P | Phillips-Van Heusen Corporation | Phillips-Van Heusen Corporation. |
| 20030252 | Apax Europe V–A, L.P | Phillips-Van Heusen Corporation | Phillips-Van Heusen Corporation. |
| 20030258 | Liberty Media Corporation | Wildblue Communications, Inc | Wildblue Communications, Inc. |
| 20030259 | Intelsat, Ltd | Wildblue Communications, Inc | Wildblue Communications, Inc. |
| **Transactions Granted Early Termination—01/09/2003** | | | |
| 20030260 | KKR Millennium Fund L.P | DTE Energy Company | International Transmission Company. |
| **Transactions Granted Early Termination—01/10/2003** | | | |
| 20030262 | Entravision Communications Corporation. | Stuart and Anita Subotnick | Big City Radio. |
| 20030263 | Emanuel J. Freidman | Foster Merger Corporation | Foster Merger Corporation. |
| 20030264 | Dairy Farmers of America, Inc | Dairy Farmers of America, Inc | Milk Products, LP. |
| 20030265 | Osborne Jay Call | St. Mary Land & Exploration Company. | St. Mary Land & Exploration Company. |
| 20030266 | Household International, Inc | Gottschalks, Inc | Gottschalks, Inc. |
| 20030267 | GTCR Fund VII, L.P | William Blair Capital Partners V, L.O. | MGP Holding Corp. |
| 20030271 | ING Furman Selz Investors III L.P. | Roadway Corporation | Arnold Transportation Services, Inc. |
| **Transactions Granted Early Termination—01/13/2003** | | | |
| 20030269 | Harry J. Pappas | Harry J. Pappas | Hispanic America of Houston, LLC.<br>Hispanic America of San Francisco, LLC. |
| **Transactions Granted Early Termination—01/14/2003** | | | |
| 20030261 | GTCR Fund VI, L.P | Integrated Health Services, Inc., (Debtor-in-Possession). | IHS Long Term Care, Inc.<br>IHS Therapy Care, Inc. |
| **Transactions Granted Early Termination—01/17/2003** | | | |
| 20030245 | Berkshire Hathaway Inc | Wabash National Corporation | Apex Trailer Leasing & Rentals, L.P. |
| 20030281 | VERITAS Software Corporation | Precise Software Solutions Ltd | Precise Software Solutions Ltd. |
| **Transactions Granted Early Termination—01/21/2003** | | | |
| 20030276 | Welsh, Carson, Anderson & Stowe IX, L.P. | AmeriPath, Inc | AmeriPath, Inc. |
| 20030277 | Welsh, Carson, Anderson & Stowe IX, L.P. | NewCo | NewCo. |
| 20030278 | Universal American Financial Corp. | Ceres Group, Inc | The Pyramid Life Insurance Company. |
| 20030284 | ABRY Broadcast Partners II, L.P | Morris Network, Inc | Morris Network of Alabama, Inc.<br>United Broadcasting Corporation. |
| 20030285 | Eastman Kodak Company | Donald J. Burrell | Burrell Colour, Inc. |
| 20030297 | Itron, Inc | Silicon Energy Corp | Silicon Energy Corp. |

| Trans # | Acquiring | Acquired | Entities |
|---|---|---|---|
| **Transactions Granted Early Termination—01/27/2003** | | | |
| 20030289 | Morgan Stanley Dean Witter Capital partners IV, L.P. | Michael Pardy | Southern Care Birmingham, Inc.<br>Southern Care Hospice, Inc.<br>Southern Care Newton, Inc.<br>Southern Hospice Care, Inc.<br>SouthernCare Systems, Inc. |
| 20030291 | Berkshire Fund VI, Limited Partnership. | Acosta, Inc | Acosta, Inc. |
| 20030292 | Berkshire Fund V, Limited Partnership. | Acosta, Inc | Acosta, Inc. |
| 20030293 | Nautic Partners V, L.P | Cortec Group Fund III, L.P | Gaymar Holdings, Inc. |
| 20030300 | K2 Inc | Rawlings Sporting Goods Company, Inc. | Rawlings Sporting Goods Company, Inc. |
| 20030301 | Sanmina-SCI Corporation | International Business Machines Corporation. | International Business Machines Corporation. |
| 20030309 | Tribune Company | ACME Communications, Inc | ACME Television Holdings of Missouri, Inc (v/s).<br>ACME Television Licenses of Oregon, LLC (Assets).<br>ACME Television of Oregon, LLC (Assets). |
| **Transactions Granted Early Termination—01/28/2003** | | | |
| 20030304 | Solectron Corporation | R–2 Group Holdings LLC | Electron Manufacturing Services, Inc. |
| 20030311 | Silgan Holdings, Inc | Amcor Limited | Amcor White Cap, LLC. |
| 20030312 | Ronald O. Perelman | SpectaGuard Acquisition LLC | SpectaGuard Acquisition LLC. |
| **Transactions Granted Early Termination—01/30/2003** | | | |
| 20030296 | EPIQ Systems, Inc | Bankruptcy Services LLC | Bankruptcy Services LLC. |
| **Transactions Granted Early Termination—01/31/2003** | | | |
| 20020479 | Dainippon Ink and Chemicals, Incorporated. | Bayer AG | Bayer Corporation. |
| 20030270 | Quadrangle Capital Partners LP | Cablevision Systems Corporation | Cablevision Systems Corporation. |
| 20030286 | Watson Pharmaceuticals, Inc | Novartis AG | Novartis Pharma AG.<br>Novartis Pharmaceuticals Corporation. |
| 20030331 | Valassis Communications, Inc | Prudential plc | NCH Marketing Services, Inc. |
| 20030338 | Great Lakes Chemical Corporation. | Dean A. Kelly | Lime-O-Sol Company. |
| 20030339 | Great Lakes Chemical Corporation. | James L. Godschalk, Jr | Lime-O-Sol Company. |
| **Transactions Granted Early Termination—02/03/2003** | | | |
| 20030298 | SunGard Data Systems Inc | Michael Picozzi, III | Andover Brokerage, LLC. |
| 20030322 | Pfizer Inc | Eyetech Pharmaceuticals, Inc | Eyetech Pharmaceuticals, Inc. |
| 20030323 | Fidelity National Financial, Inc | Private Equity Investors III, L.P | Lender's Service Holdings, Inc.<br>Lender's Service, Inc. |
| 20030324 | Fidelity National Financial, Inc | Equity-Linked Investors-II | Lender's Service Holdings, Inc.<br>Lender's Service, Inc. |
| 20030337 | Collins Stewart Holdings plc | Tullett plc | Tullett plc. |
| **Transactions Granted Early Termination—02/04/2003** | | | |
| 20030321 | Fomento Economico Mexicano, S.A. de C.V.. | Panamerican Beverages, Inc | Panamerican Beverages, Inc. |
| 20030330 | Mr. Graeme Hart | Burns, Philip & Company Limited | Burns, Philip & Company Limited. |
| **Transactions Granted Early Termination—02/05/2003** | | | |
| 20030128 | Pilot Corporation | The Williams Companies, Inc | Williams TravelCenters, Inc. |
| **Transactions Granted Early Termination—02/07/2003** | | | |
| 20030129 | Marathon Oil Corporation | The Williams Companies, Inc | Williams TravelCenters, Inc. |
| **Transactions Granted Early Termination—02/10/2003** | | | |
| 20030189 | The Lundbeck Foundation | Synaptic Pharmaceutical Corporation. | Synaptic Pharmaceutical Corporation. |
| 20030280 | Verizon Communications Inc | Cablevision Systems Corporation | Boston Holding, LLC.<br>New York PCS Holding, LLC.<br>Northcoast Communications, L.L.C. |

| Trans # | Acquiring | Acquired | Entities |
|---|---|---|---|
| 20030340 | Fidelity National Financial, Inc | ANFI, Inc | ANFI, Inc. |
| 20030343 | Level 3 Communications, Inc | Carl C. Icahn | XO Communications, Inc. |
| 20030353 | Heartland Industrial Partners, L.P | Linsalata Capital Partners Fund II, L.P. | Highland Group Corporation. |
| 20030354 | Prudential Financial, Inc | Skandia Insurance Company Ltd. (publ). | Skandia U.S. Inc. |
| **Transactions Granted Early Termination—02/12/2003** | | | |
| 20030328 | Pearson plc | The McGraw-Hill Companies, Inc | S&P Comstock, Inc. |
| 20030342 | Manulife Financial Corporation | Canada Life Financial Corporation. | Canada Life Financial Corporation. |
| 20030345 | The Coca-Cola Company | Coca-Cola Enterprises Inc | Truesdale Packaging Company LLC. |
| 20030349 | Forrester Research, Inc | Giga Information Group, Inc | Giga Information Group, Inc. |
| 20030356 | Nichimen Corporation | Nissho Iwai Corporation | Nissho Iwai Corporation. |
| 20030357 | Nissho Iwai Corporation | Nichimen Corporation | Nichimen Corporation. |
| 20030359 | ALLTEL Corporation | Cellular North Michigan Network General Partnership. | Cellular North Michigan Network General Partnership. |
| **Transactions Granted Early Termination—02/14/2003** | | | |
| 20030305 | Sunrise Assisted Living, Inc | Marriott International, Inc | Marriott Senior Living Services, Inc. |
| 20030326 | Hertal Acquisition plc | Riverdeep Group plc | Riverdeep Group plc. |
| 20030347 | The Bank of New York Company, Inc. | Credit Suisse Group | iNautix Technologies, LLC.<br>Pershing Limited.<br>Pershing LLC.<br>Pershing Trading Company, L.P. |
| 20030362 | ALLTEL Corporation | Fidelity National Financial, Inc | Fidelity National Financial, Inc. |
| 20030363 | Fidelity National Financial, Inc | ALLTEL Corporation | ALLTEL Information Services, Inc. |
| 20030369 | Energizer Holdings, Inc | Pfizer Inc | N.V. Wilkinson Sword S.A. (Belgium).<br>Pfizer Inc.<br>Schnick North America, Inc.<br>Warner-Lambert Trading Co. Ltd. (Hong Kong).<br>Wilkinson Sword—Productos de Higiene, Lda (Portugal).<br>Wilkinson Sword GmbH (Austria).<br>Wilkinson Sword GmbH (Germany).<br>Wilkinson Sword Limited (UK).<br>Wilkinson Sword S.A.E. (Spain).<br>Wilkinson Sword S.p.A. (Italy).<br>Wilkinson Sword Verwaltungs-GmbH (Germany).<br>Wilkinson-Sword B.V. (Netherlands). |
| 20030376 | Valero L.P | Valero Energy Corporation | Valero Pipeline Company.<br>Valero refining Company-California.<br>Valero Refining-Texas, L.P. |
| 20030379 | Canadian Oil Sands Trust | EnCana Corporation | AEC Oil Sands GP Ltd. |
| **Transactions Granted Early Termination—02/19/2003** | | | |
| 20030368 | Qwest Communications International Inc. | Qwest Communications International Inc. | TW Wireless, L.L.C. |
| **Transactions Granted Early Termination—02/20/2003** | | | |
| 20030348 | Techtronic Industries Co., Ltd | Royal Appliance Mfg. Co | Royal Appliance Mfg. Co. |
| **Transactions Granted Early Termination—02/21/2003** | | | |
| 20030344 | Odyssey Investment Partners Fund, LP. | Trans Technology Corporation | Norco, Inc. |
| 20030364 | National Bedding Company | Citigroup Inc | Sleepmaster LLC. |
| 20030377 | Morgenthaler Partners VI, L.P | WCM Beteiligungs—und Grundbesitz—Aktiengesellschaft. | MPI International Inc. |
| 20030378 | Matrix Service Company | Frank W. Hake, II | Hake Group, Inc. |

**FOR FURTHER INFORMATION CONTACT:** Sandra M. Peay or Renee A. Hallman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580. (202) 326–3100.

By Direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 03–6077 Filed 3–12–03; 8:45 am]

BILLING CODE 6750–01–M

## FEDERAL TRADE COMMISSION

**[File Nos. 001 0221, 011 0046, and 021 0181]**

## Bristol-Myers Squibb Company; Analysis To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before April 7, 2003.

**ADDRESSES:** Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov,* as prescribed below.

**FOR FURTHER INFORMATION CONTACT:** Susan Creighton or Jeffrey Brennan, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–2946 or 326–3688.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 7, 2003), on the World Wide Web, at *http://www.ftc.gov/os/2003/03/index.htm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: *consentagreement@ftc.gov.* Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii)).

### Analysis To Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Bristol-Myers Squibb Corporation (BMS). The proposed consent order would settle charges that BMS engaged in a series of unlawful acts to delay competition from generic versions of three of its major drug products. The proposed consent order has been placed on the public record for 30 days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by BMS that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

The complaint charges that BMS engaged in a series of anticompetitive acts over the past decade to obstruct the entry of low-cost generic competition to three highly profitable BMS prescription drug products: BuSpar, an anti-anxiety agent; and two anti-cancer drugs, Taxol and Platinol. According to the complaint, when confronted with imminent competition to these drugs through generic entry, BMS undertook a course of conduct that includes: paying a would-be competitor $72.5 million to abandon its challenge to a BMS patent and stay off the market until the patent expired; abusing Food and Drug Administration (FDA) regulations to block generic entry; making false statements to the FDA in connection with listing patents in the Orange Book; engaging in inequitable conduct before the U.S. Patent and Trademark Office (PTO) to obtain patents; and filing baseless patent infringement suits. As a result, the complaint alleges, consumers were forced to incur hundreds of millions of dollars in additional costs to obtain vital prescription drug products.

The proposed order is designed to remedy the pattern of unlawful conduct charged in the complaint and prevent recurrence of such conduct, while maintaining BMS's ability to engage in legitimate activities that may promote innovation and benefit consumers.

### Background

The proposed consent order rests in substantial part on charges that BMS abused governmental processes to delay generic competition to three of its highly successful prescription drug products and, in particular, that it misused the regulatory scheme established by Congress to expedite the approval of generic drugs.

A generic drug is a pharmaceutical product that contains the same active ingredients as its brand-name counterpart and is ''bioequivalent'' to the branded drug, that is, the FDA has determined there is no significant difference in the rate and extent of absorption of the two products. Generic drugs typically are sold at substantial discounts from the branded drug's price. A Congressional Budget Office report estimates that purchasers saved $8–10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand-name product.[1]

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the ''Hatch-Waxman Act,'' to facilitate the entry of lower-priced generic drugs, while maintaining incentives for companies to invest in research and development of new drugs. A company seeking approval from the FDA to market a new drug must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. To receive FDA approval to market a generic version of a branded drug, a company files an Abbreviated New Drug Application (ANDA) demonstrating that its product is bio-equivalent to its branded counterpart, but need not provide independent data on safety and efficacy.

The Hatch-Waxman Act established certain rights and procedures that apply when a company seeks approval from the FDA to market a generic product prior to the expiration of a patent or patents relating to the branded drug upon which the generic is based. An NDA applicant is required to submit to the FDA information on certain types of patents relating to the approved drug. The FDA lists the approved drug and its related patents in a publication entitled

[1] Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry xiii, 13 (July 1998).

''Approved Drug Products with Therapeutic Equivalence Evaluations,'' commonly known as the ''Orange Book.'' If the PTO grants a patent relating to an approved drug after the NDA has been approved, and the NDA holder submits it for listing in the Orange Book, then the FDA will list it as well.

The listing of patents in the Orange Book plays a substantial role in the timing of FDA approval of generic drugs. As part of the ANDA process, the ANDA filer must certify to the FDA regarding its generic product and any patents listed in the Orange Book that claim the reference branded drug. If the ANDA filer seeks approval before the expiration of all listed patents, it must: (1) File what is known as a ''Paragraph IV certification,'' declaring that the patents listed in the Orange Book either are invalid or will not be infringed by the manufacture, use, or sale of the drug products for which the ANDA is submitted; and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days of the notification, FDA approval to market the generic drug is automatically stayed for 30 months, regardless of the merits of the suit, unless before that time the patent expires or a court holds that the patent is invalid or not infringed.

Not all patents are eligible for listing in the Orange Book and the special statutory 30-month stay that the Hatch-Waxman Act provides. The statute provides for listing only if: (1) The patent ''claims the drug * * * or a method of using such drug'' and (2) the patent is one ''with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug.'' [2] In the case of patents not eligible for listing in the Orange Book, a branded firm still can sue a generic company for patent infringement, but under ordinary federal litigation procedures and without the benefit of an automatic 30-month stay. To prevent sale of the generic product before conclusion of the suit in such cases, a branded firm must obtain a preliminary injunction, which requires that it demonstrate a likelihood of success on the merits, among other factors.

Although Orange Book listings have significant legal and competitive implications, it is private parties, rather than the FDA, that in practice determine whether patents are listed. The FDA has repeatedly stated that its role in patent listings is solely ministerial and that it lacks the resources and expertise to scrutinize patent information in the Orange Book. Even when a generic applicant disputes a patent listing, the FDA merely asks the NDA holder to confirm that the listed patent information is correct. Unless the NDA holder itself withdraws or amends its listed patent information, the FDA will not remove the patent listings from the Orange Book.[3] Thus, as one court has stated, ''the FDA's listing should not create any presumption that [a] patent was correctly listed.'' [4] In addition, the Federal Circuit has held that generic applicants have no right to bring a declaratory judgment action to challenge an NDA holder's Orange Book listing as improper.[5] As long as the patent remains listed, the brand-name company can continue to benefit from the availability of an automatic 30-month stay of FDA approval of ANDAs, by initiating a patent suit against generic applicants.

The Commission's recent study, Generic Drug Entry Prior to Patent Expiration (July 2002), examined the potential for abuse of the Hatch-Waxman process for Orange Book listings and 30-month stays.[6] The data received by the Commission showed that brand-name companies are increasingly listing in the Orange Book, and suing on, multiple patents, and that these are frequently patents that have been listed after an ANDA has been filed. If patents issued to the brand-name company are listed before the generic applicant files its ANDA, then a brand-name company's suit on those patents will generate a single 30-month stay, even though multiple patents are at issue in the litigation. If the patent is obtained and listed after the generic applicant has filed its ANDA, however, then the brand-name company can obtain an additional 30-month stay (which may be consecutive to or overlap the first 30-month stay) following a generic applicant's certification that it does not infringe the later-issued patent. The FTC Study found that for drugs for which there were multiple 30-month stays, the additional delay of FDA approval (beyond the first 30 months) ranged from four to 40 months. The FTC Study also found that later-issued patents frequently raise listability or validity concerns. Of the eight drug products involving later-issued patents identified in the study, all four that had been adjudicated were found invalid or not infringed. Of the eight drug products involving later-issued patents identified in the study, three involve the BMS products that are the subject of the complaint here.[7]

**The Challenged Conduct**

The complaint makes the following allegations:

*A. BuSpar*

BuSpar is used to treat persistent anxiety, a condition affecting an estimated 10 million Americans. BMS began selling BuSpar in 1986, and by 2000, the year before a generic version became available, BuSpar sales in the United States were over $600 million.

The complaint charges that BMS first entered into an unlawful patent settlement agreement, in which it agreed to pay a potential generic competitor over $70 million to withhold its generic version of BuSpar from the market until BMS's patent expired, and then provided false and misleading information to the FDA to induce the FDA to list a later patent on BuSpar in the Orange Book, one that did not meet either of the statutory requirements for listing. Additionally, the complaint alleges that BMS filed baseless patent infringement suits against generic applicants on BuSpar.

The settlement agreement arose out of patent litigation that BMS filed after Schein Pharmaceutical, Inc. submitted an ANDA for generic buspirone hydrochloride (buspirone), the active ingredient in BuSpar. Schein filed a Paragraph IV certification with the FDA in 1992, contending that BMS's '763 patent was invalid, because it claimed a use of buspirone that had been anticipated by an earlier BMS patent. BMS's suit triggered a 30-month stay on FDA approval of Schein's ANDA, which would have expired in early 1995.

In December 1994, BMS entered into an agreement with Schein to settle their patent litigation. Pursuant to that agreement, BMS agreed to pay Schein $72.5 million over the next four years, and Schein agreed to refrain from marketing its ANDA product or any other generic version of BuSpar (regardless of whether such product

[2] 21 U.S.C. 355(b)(1); 355(c)(2); 355(j)(7)(A)(iii) (2003).

[3] See, e.g., *American Bioscience, Inc.* v. *Thompson,* 269 F.3d 1077, 1080 (D.C. Cir. 2001) (recognizing that the FDA ''has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders' patent declarations and following their listing instructions'').

[4] *Ben Venue Labs., Inc.* v. *Novartis Pharm. Corp.,* 10 F. Supp. 2d 446, 456 (D.N.J. 1998).

[5] See *Mylan Pharms., Inc.* v. *Thompson,* 268 F.3d 1323, 1329–33 (Fed. Cir. 2001).

[6] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), available at *http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.*

[7] Generic Drug Study at 39–40, 48–50.

would infringe BMS's patent), until the '763 patent expired. Schein also agreed to acknowledge the validity of the '763 patent, to refrain from assisting others in challenging the '763 patent or in developing generic buspirone, and to take other steps to help BMS protect its patent from another challenge to its validity.

Anticipating expiration of its '763 patent in November 2000, BMS filed a new patent application with the PTO in 1999, involving the use of buspirone to create the metabolite of buspirone (a metabolite is the new molecule created when a pharmaceutical agent breaks down in the body). The PTO, however, repeatedly rejected BMS's efforts because BMS had been making and selling BuSpar to treat anxiety in the United States for nearly 14 years. Only after BMS finally requested a patent that claimed solely the use of the metabolite of buspirone—not the use of buspirone itself—and only hours before the '763 patent was due to expire, did the PTO issue what became known as the '365 patent. BMS promptly submitted the '365 patent information to the FDA for listing in the Orange Book.

BMS's '365 patent did not meet either of the statutory requirements for listing a patent in the Orange Book, because it does not claim BuSpar or a method of using BuSpar, and it is not a patent with respect to which a claim of patent infringement could reasonably be asserted against someone selling BuSpar. Although BMS knew that it had only obtained a patent claiming a method of using a metabolite, it nonetheless submitted a declaration to the FDA affirming that the '365 patent claimed a method of using BuSpar, in order to list the patent in the Orange Book. Furthermore, BMS intentionally made an additional false and misleading statement after ANDA filers on BuSpar asserted to the FDA that the '365 patent did not meet the criteria for listing in the Orange Book. The FDA asked BMS to provide a declaration that the '365 patent contains a claim for an approved use of buspirone. BMS responded with a declaration expressly affirming that the '365 patent does in fact claim the approved uses of buspirone, a statement that was false and directly contradicted representations BMS made to the PTO to obtain the '365 patent. Consistent with its ministerial approach to Orange Book listings, the FDA simply accepted BMS's statements and deemed the '365 patent listed in the Orange Book as of November 21, 2000. In so doing, FDA noted that it listed the patent solely on the basis of BMS's declarations that the patent met the requirements for listing and did not make any independent determination regarding the '365 patent's scope and coverage.

The complaint charges that BMS knew that its representations to the FDA—to the effect that the '365 patent claimed a method of using buspirone—were false and misleading. BMS made these misrepresentations purposely and intentionally, to obtain an improper Orange Book listing of the '365 patent. Through its wrongful listing in the Orange Book of the '365 patent, BMS illegitimately acquired the ability to trigger a 30-month stay, thereby delaying entry of generic buspirone and depriving consumers of lower prices and other benefits of competition.

Generic competition to BuSpar occurred only after the '365 patent was removed from the Orange Book in March 2001, following the decision by the district court in *Mylan Pharmaceuticals, Inc.* v. *Thompson,* 139 F. Supp. 2d 1 (D.D.C. 2001), ordering BMS to seek de-listing.[8] This competition occurred substantially later than it would have absent BMS's anticompetitive acts. As a consequence, consumers suffered substantial economic detriment by paying monopoly prices for an unjustifiably extended period.

The complaint also charges that the patent infringement suits BMS brought against ANDA filers for infringement of the '365 patent were objectively baseless and filed without regard to their merits. The '365 patent could not be both valid and infringed. If the patent claim were interpreted to cover the currently-approved uses for which the generic applicants submitted their ANDAs—necessary to demonstrate that the ANDA products infringed—then the patent necessarily would be invalid, because those uses had been known long before BMS applied for the patent. A court later so found on summary judgment.[9] The intent and effect of BMS's suits, the complaint states, was to wrongfully trigger the 30-month stay as a means of preventing generic buspirone manufacturers from marketing their products.

*B. Taxol*

Taxol is used to treat cancers of the ovaries, breasts and lungs, and AIDS-related Kaposi's sarcoma. The drug's active ingredient, paclitaxel, is a naturally-occurring substance whose antic-cancer properties were discovered and developed by scientists at the National Cancer Institute (NCI). In 1991, the NCI gave BMS the exclusive right to use existing and future data for FDA approval of paclitaxel, and BMS obtained FDA approval to market Taxol in 1992. Prior to generic entry in 2000, BMS's annual Taxol sales in the United States were over $1 billion.

The complaint charges that BMS used many of the same strategies to obstruct generic competition to Taxol that it used with BuSpar: improperly listing patents in the Orange Book (three patents in the case of Taxol); and abusing the regulatory process through the filing of misrepresentations. In addition, the complaint alleges that BMS entered into an unlawful agreement with another firm for the purpose of furthering its effort to obtain another 30-month stay on FDA approval of generic versions of Taxol.

In 1992, although it told a Congressional committee that ''near-term generic competition for TAXOL is a certainty,'' because Taxol was not a patented product, BMS in fact was actively pursuing a patent application before the PTO on Taxol. In prosecuting that patent application before the PTO, BMS made representations that were directly contrary to what it had previously told the FDA in seeking approval of its NDA for Taxol.

To obtain FDA approval of its NDA, BMS had relied on several studies in the public domain to show that Taxol was safe and effective. Because the NCI funded the discovery and initial development of paclitaxel as an anti-cancer drug, much of the research relating to Taxol was in the public domain, so the results of that research were unpatentable. To obtain a patent, BMS had to demonstrate to the PTO that its claimed method of administering Taxol differed from the methods used in those prior studies

BMS told the PTO that certain studies (ones it had relied on to obtain FDA approval for Taxol) did not provide evidence of safety and efficacy, and thus made various statements about the studies that are directly contrary to those BMS made to the FDA. In addition, BMS also deliberately failed to disclose to the PTO material prior art. In making false and misleading material statements to the PTO and by failing to disclose material prior art, BMS breached its duty of candor and good faith in dealing with the PTO. BMS therefore engaged in inequitable conduct, rendering the two patents that resulted (the '537 and '803 patents) unenforceable.

[8] The Federal Circuit later reversed this ruling on jurisdictional grounds. *Mylan Pharms., Inc.* v. *Thompson,* 268 F.3d 1323, 1329–33 (Fed. Cir. 2001) (holding no private right of action under the Federal Food, Drug, and Cosmetic Act to seek de-listing).

[9] *In re Buspirone Patent Litig.,* 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002); *In re Buspirone Antitrust Litig.,* 183 F. Supp.2d 363, 376 (S.D.N.Y. 2002).

Because BMS knew that the '537 and '803 patents were obtained through inequitable conduct before the PTO, it could not reasonably believe that the patents were enforceable or consequently that they were listable under the FDA's Orange Book regulations. Nevertheless, BMS promptly submitted the patents to the FDA for listing in the Orange Book. Furthermore, after a number of generic pharmaceutical manufacturers filed ANDAs with Paragraph IV certifications, BMS brought patent infringement suits—based on patents it knew it had obtained through inequitable conduct—that triggered Hatch-Waxman's automatic 30-month stay provision, insulating Taxol from potential generic drug competition for that period.

Finally, BMS improperly listed a third patent in the Orange Book and thereby obtained the ability to trigger the Hatch-Waxman provision for another 30-month stay as a result of a conspiracy with American Bioscience, Inc. (ABI). Shortly after the 30-month stays that BMS had obtained from its unlawful listings of the '537 and '803 patents expired, but before any ANDAs for generic paclitaxel obtained FDA approval, BMS and ABI agreed on the terms of an option to license ABI's '331 patent. The agreement provided that ABI would receive royalties based on a significant percentage of BMS sales of Taxol, an arrangement that would be highly profitable to ABI if BMS continued to enjoy protection from generic competition to Taxol.

BMS submitted the '331 patent to the FDA for listing in the Orange Book, but it could not have reasonably believed that the relevant claims of the '331 patent were valid, or consequently that the '331 patent should be listed in the Orange Book as claiming Taxol. BMS knew of material prior art that invalidated the relevant claims of the '331 patent. Moreover, BMS's own experience with the sale and use of Taxol prior to that date invalidated the relevant claims of the '331 patent.

*C. Platinol*

Platinol is used in chemotherapy to treat various forms of cancer. BMS began selling Platinol in 1978 and Platinol-AQ in 1988, and annual United States sales of its Platinol products were $100 million by 1998. Platinol's active pharmaceutical ingredient is cisplatin.

Regarding Platinol, the complaint alleges that, as with BuSpar and Taxol, BMS wrongfully submitted a patent for listing in the Orange Book to obtain an unwarranted 30-month stay on FDA approval of competing generic products. By 1996, BMS's patent protection for its Platinol products was running out, and four would-be generic rivals were poised to enter with their lower-cost, bioequivalent products. Facing likely generic competition to its Platinol monopoly for the first time, BMS, which held an exclusive license to cisplatin, and the licensor decided to amend a patent application then pending at the PTO—an application that had been initially filed more than two decades earlier, in 1970. In October 1996—just two months before BMS's other Platinol patents were to expire—the PTO issued the '925 patent based on this amended application. BMS promptly submitted this new patent for listing in the Orange Book. This listing, coupled with BMS's initiation of a patent infringement lawsuit in federal court against each generic cisplatin applicant, triggered an automatic statutory 30-month stay on FDA approval of the generic applications.

According to the complaint, BMS could not have reasonably believed that the '925 patent was valid, and its listing of the patent in the Orange Book was not made in good faith to comply with FDA regulations. In fact, in October 1999, a district court ultimately found, by clear and convincing evidence, that the '925 patent was invalid for obviousness-type double patenting, a ruling that the Federal Circuit later upheld. As a result of BMS's wrongful listing of the '925 patent, consumers were deprived, for about two years, of the benefits of a lower-priced generic alternative to BMS's branded cisplatin products.

**Competitive Analysis**

The complaint alleges that the relevant product markets in which to assess the competitive effects of BMS's conduct are:

- Buspirone-based products (BuSpar and generic bioequivalent versions of BuSpar);
- Paclitaxel-based products (Taxol and generic bioequivalent versions of Taxol); and
- Cisplatin-based products (Platinol and generic bioequivalent versions of Platinol).

In each market, according to the complaint, entry of a lower-priced generic version of BMS's product resulted in a significant, immediate decrease in the sales of the BMS product and led to a significant reduction in the average price for products in the relevant market. Conversely, the complaint states that the availability of other therapeutic agents for the conditions that BuSpar, Taxol, and Platinol treat was not sufficient to prevent the effects from BMS's conduct. As a result of this competitive relationship between each of the three BMS branded products and its generic bioequivalents, each of these groups of products comprises a distinct relevant product market for purposes of analyzing the challenged conduct here.

According to the complaint, the relevant geographic market in which to assess the competitive effects of BMS's conduct is the United States, given the FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals such as those at issue here occur on a nationwide basis.

The complaint alleges that, prior to the entry of generic versions of its BuSpar, Taxol, and Platinol products, BMS had monopoly power in each of the three relevant antitrust markets. BMS is charged with engaging in acts that willfully maintained its monopolies in buspirone, paclitaxel, and cisplatin products, thereby violating Section 5 of the FTC Act. In addition, the complaint charges that BMS agreed with Schein to settle patent litigation by paying Schein not to compete until the patent expired, and agreed with ABI to wrongfully list ABI's '331 patent, and challenges those agreements as acts of monopolization and as unreasonable restraints of trade in violation of Section 5.

Exclusionary conduct by a monopolist that is reasonably capable of significantly contributing to the maintenance of the firm's dominance gives rise to substantial competitive concerns.[10] The conduct alleged in the complaint creates such concerns.

By listing patents in the Orange Book that did not meet the statutory requirements for such listings, BMS, according to the complaint, acquired the ability to trigger the Hatch-Waxman 30-month stay provision on FDA approval of competing generic products. An NDA with monopoly power has an incentive to make improper listings to protect its monopolies. In addition, NDA holders have the ability to make wrongful listings because the FDA does not police listings to ensure they meet regulatory requirements prior to publishing them in the Orange Book.[11] The Orange Book

[10] *Barry Wright Corp.* v. *ITT Grinnell Corp.,* 724 F.2d 227, 230 (1st Cir. 1983) (Breyer, J.) (citing 3 P. Areeda & D. Turner, Antitrust Law, ¶ 626 at 83 (1978)); see also *Aspen Skiing Co.* v. *Aspen Highlands Skiing Co.,* 472 U.S. 585, 596 n.20 (1985); *Lorain Journal Co.* v. *United States,* 342 U.S. 143, 154 n.7 (1951).

[11] As a recent court decision expressly recognized, ''[t]he duty to ensure that the Orange Book only lists patents that actually claim approved drugs * * * lies with NDA holders.'' *Purepac*

Continued

listing scheme established by Congress assumes and requires that NDA holders act in good faith in listing patents. Listings that are not based on a reasonable, good faith belief that the patent is listable thus cannot be justified on grounds that the NDA holder was merely complying with Hatch-Waxman listing regulations.[12] The complaint alleges for each of the challenged listings that BMS lacked a reasonable belief that the patents were listable, and that it listed the patents to block generic competition, not in good faith compliance with FDA regulations.

Indeed, the complaint charges that BMS misled the FDA about the scope, validity, and enforceability of its patents. In listing the '365 patent on BuSpar, the complaint alleges, BMS intentionally made false and misleading statements to the FDA to obtain a wrongful Orange Book listing. Similarly, the charges concerning two of the Taxol patents (the '537 and '803 patents) involve allegations that BMS submitted the patents for listing knowing that it had engaged in inequitable conduct before the PTO, deliberately making misleading statements and concealing material prior art, as part of a scheme to abuse Hatch-Waxman processes and thereby extend its monopoly in paclitaxel. Under well-established patent law, inequitable conduct in obtaining a patent makes the patent unenforceable.[13] But the Orange Book listing scheme is susceptible to opportunistic behavior. The NDA holder can exploit the listing scheme by obtaining patents and listing them in the Orange Book to block FDA approvals of generic rivals for 30 months, even when the NDA holder does not reasonably expect the patents to ultimately hold up in court.

Finally, with respect to two other patents (ABI's '331 patent on Taxol and the '925 patent on Platinol), the complaint alleges that BMS submitted the listings while fully aware of facts and law that made the patents invalid. Although the Hatch-Waxman Paragraph IV certification process contemplates that some patents that are listed may ultimately be found invalid or unenforceable, it does not contemplate NDA holders listing a patent without a reasonable belief that the patent meets the listing requirements in order to use the 30-month stay provision as a weapon against generic rivals. Moreover, the pattern of conduct that BMS is charged with having engaged in reinforces the charge that BMS acted with an intent to abuse the listing process to extend its monopolies in all three drugs.

BMS's alleged initiation of baseless lawsuits to trigger the 30-month stay provision and inflict competitive harm through the process, rather than through the outcome, of the suit likewise amounts to exclusionary conduct to maintain BMS's monopoly in buspirone products.

Two of BMS's challenged acts were taken in concert with other firms, and the complaint challenges these acts both as monopoly maintenance and as agreements that unreasonably restrain trade in violation of Section 5. First, BMS's settlement with Schein, in which BMS is alleged to have agreed to pay its potential competitor in the buspirone market to withhold competition until patent expiration, eliminated the only potential generic threat to BuSpar for the entire patent period. Such action not only would have deprived consumers of the potential, albeit uncertain, competition from Schein, but also would have given BMS time to implement what the complaint charges was a further strategy to obstruct competition to BuSpar, obtaining and wrongfully listing the '365 patent. The complaint alleges that the settlement agreement has no legitimate justification, harms consumers, and is unlawful.

BMS's agreement with ABI to list ABI's '331 patent likewise involves charges of an unjustified agreement to obstruct generic competition and share monopoly profits. As set forth in the complaint, for both parties, the value of the patent license that ABI agreed to sell to BMS lay in its ability to trigger a 30-month stay under Hatch-Waxman: Delayed generic entry would protect BMS's revenues, and the terms of the option to license meant that ABI would receive more in royalty payments from BMS if BMS continued to hold a monopoly in paclitaxel products.

Because most of the acts challenged in this matter involve use of governmental processes, the complaint also affirmatively pleads that BMS's conduct is not immune from antitrust liability under the Noerr-Pennington doctrine, which protects private parties' petitioning for governmental action. First, BMS's Orange Book submissions of five patents (one on BuSpar, three on Taxol, and one on Platinol) cannot qualify for *Noerr* immunity because they do not constitute petitioning behavior. As the court in *In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002), observed in rejecting BMS's claim of *Noerr* protection, Orange Book filings involve no petitioning because the FDA merely accepts the NDA holder's representations and exercises no intervening judgment. In addition, Orange Book filings are not entitled to Noerr protection as conduct incidental to petitioning by means of a patent infringement suit. The fact that infringement litigation triggers a statutory delay in FDA approval does not render the Orange Book listing incidental to the litigation. An NDA holder can bring an infringement suit regardless of whether its patents are listed in the Orange Book. Id. at 372.[14] Furthermore, BMS's filings and other statements to the FDA are alleged to involve knowing and material misrepresentations, and would therefore fall outside the protection of the Noerr doctrine for that reason as well.

The challenged settlement agreement between BMS and Schein likewise is neither petitioning nor the kind of action incidental to petitioning that the Noerr doctrine immunizes.[15]

Second, with respect to challenged BMS actions that do involve petitioning of government (for example, the patent infringement suits involving BuSpar), the complaint alleges that BMS's actions fall outside the protections of the Noerr doctrine. Regarding the lawsuits, the complaint alleges that they were objectively baseless and brought to injure a competitor through the process, rather than the outcome, of the litigation. As a result, they satisfy the two-part test for the sham litigation exception to Noerr set forth in *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Industries., Inc.,* 508 U.S. 49 (1993).

Finally, the logic and policy underlying the Supreme Court's decision in *California Motor Transport Co.* v. *Trucking Unlimited,* 404 U.S. 508 (1972), which held a pattern of filings undertaken without regard to their merits to be outside the protections of Noerr, supports the application of a pattern exception for BMS's alleged pattern of conduct across its buspirone, paclitaxel, and cisplatin products, and

*Pharm.* v. *Thompson,* 2002 WL 31840631, at *5 (D.D.C. Dec 16, 2002).

[12] See, e.g., *Southern Pac. Communications Co.* v. *AT&T,* 740 F.2d 980, 1009 (D.C. Cir. 1984) (AT&T's conduct in meeting regulations governing its obligations for interconnecting other long distance carriers with its local service network can only be justified if it "is reasonable and if AT&T actually made its decision at the time in good faith on that basis rather than solely on the basis of competitive considerations.").

[13] *Precision Instrument Mfg. Co.* v. *Automotive Maintenance Mach. Co.,* 324 U.S. 806 (1945).

[14] See also Memorandum of Law of *Amicus Curiae* Federal Trade Commission in Opposition to Defendant's Motion to Dismiss (Jan. 8, 2002) in *In re Buspirone Antitrust Litig.,* 185 F.Supp. 2d 363 (S.D.N.Y. 2002), available at *http://www.ftc.gov/os/2002/01/busparbrief.pdf.*

[15] See *Andrx Pharms.* v. *Biovail Corp. Int'l,* 256 F.3d 799, 817–19 (D.C. Cir. 2001).

thus provides a separate reason to reject Noerr immunity here. As is reflected in the complaint, the overall course of conduct challenged here constitutes a clear and systematic pattern of anticompetitive misuse of governmental processes, that is, abusive filings undertaken without regard to the merits, in order to use administrative and judicial processes—rather than the outcome of those processes—as a weapon to obstruct competition. Just as the repeated filing of lawsuits brought without regard to the merits, and for the purpose of using the judicial process (as opposed to the outcome of the process), warrants rejection of Noerr immunity, so too do the alleged repeated filing of patents on the Orange Book without regard to their validity, enforceability, or listability; repeated filing of recklessly or deliberately false statements with government agencies; and filing of lawsuits brought with or without regard to the merits, also cause the actions challenged here to fall outside the scope of Noerr's protection.

By issuing the complaint in this matter along with the proposed consent agreement, the Commission finds reason to believe that BMS engaged in the alleged violations of law set forth in the complaint.

**The Proposed Order**

The proposed order is designed to maintain BMS's incentives to engage in legitimate conduct that could promote innovation, while ensuring protection of consumers through:

- Prohibitions regarding the listing and enforcement of patents relating to specific BMS products at issue here;
- General prohibitions concerning the listing and enforcement of patents; and
- Prohibitions concerning settlement of patent litigation and other agreements between an NDA holder and an ANDA filer.

*Product-Specific Provisions*

Paragraphs II through V directly address complaint charges concerning BMS's unlawful conduct regarding patents relating to BuSpar and Taxol. The proposed order does not provide similar specific relief for Platinol, because the only unexpired Platinol patent was conclusively held invalid.

The complaint alleges that the '365 patent relating to BuSpar does not cover any uses of buspirone, and a district court has so held.[16] Accordingly, to prevent future abusive listing of the '365 patent,[17] Paragraph II bars BMS from seeking to list the '365 patent in the Orange Book in relation to any NDA in which the active ingredient is buspirone. This provision will prevent BMS from seeking to list the '365 patent in connection with another buspirone product, for example a new dosage strength or formulation of BuSpar, as well as with its current BuSpar NDA.

The limitation on attempts to enforce the '365 patent is similar, but allows for the possibility that BMS might in the future have a legitimate claim of infringement. Thus, Paragraph V bars BMS from seeking to enforce the '365 patent against a product, or use of a product, that contains buspirone, except that such enforcement is permitted if the drug product in question also contains the metabolite that is the subject of the '365 patent (the 6-Hydrodroxy-metabolite of Buspirone) and the infringement claim is based on that metabolite.[18] Should such a case arise, BMS would not obtain an automatic 30-month stay on FDA approval (because of the bar on listing in Paragraph II), but, like any patent holder, it could seek a preliminary injunction from the court hearing the infringement case.

With respect to Taxol, the proposed order generally bars BMS from seeking to enforce, or collecting royalties on, any ''Taxol Patent'' if the infringement claim involves the use of ''Taxol.'' The proposed order defines ''Taxol'' to be any BMS paclitaxel drug product sold as of October 2002. As a result, this provision would not apply to any new form of Taxol that BMS might develop, and thus it would maintain BMS's incentives to pursue such innovation. With respect to BMS's existing Taxol product, however, the proposed order's bar on enforcement and royalties would apply not only to BMS's '537 and '803 patents (patents that the complaint alleges are unenforceable because of inequitable conduct by BMS before the PTO), but also to any other U.S. patent claiming Taxol as a composition of matter or a method of using Taxol (by virtue of the definition of ''Taxol Patent'' in Paragraph I.EE). Any such patent for the existing Taxol product would almost certainly be invalid, as a result of the sale of Taxol since 1992 and the extensive prior art in the public domain.

Paragraph IV of the proposed order bars BMS from taking any action to obtain or maintain a statutory 30-month stay on FDA approval with respect to an ANDA that references BuSpar or Taxol. There have already been multiple 30-month stays in connection with both of these drugs, and this provision makes it clear that further stays would be improper. At the same time, the proposed order would preserve incentives to innovate by allowing 30-month stays on new NDAs, even if those NDAs are related to BuSpar and Taxol.

*General Prohibitions Concerning the Listing and Enforcement of Patents*

Because improper Orange Book listings have a significant potential to obstruct competition and harm consumers, the proposed order contains general prohibitions designed to deter improper listings and to prevent BMS from triggering the Hatch-Waxman automatic 30-month stay in circumstances that could improperly block generic entry. Thus, the proposed order's Paragraph VI would bar BMS from Orange Book listings that are contrary to the statutes and regulations governing such listings. For example, this provision would prohibit listing patents in the Orange Book that do not actually claim the drug product at issue. This provision is similar to one contained in the consent order issued in Biovail Corp., FTC Dkt. No. C–4060 (Oct. 2, 2002).

In addition, Paragraph VII bars BMS from acting to obtain or maintain a Hatch-Waxman 30-month stay on FDA approval in certain specified situations. Because this provision does not bar Orange Book listings, ANDA filers would continue to get notice through the Orange Book of patents relating to the reference drug. Although the provision prohibits BMS from suing to trigger the automatic 30-month stay, BMS could still bring an infringement suit and avail itself of the procedures available to patent holders generally, including seeking a preliminary injunction against market entry by the generic applicant.

Paragraph VII.A prohibits BMS from triggering a 30-month stay when the patent is listed after the filing of any ANDA referencing the NDA. The Commission's Generic Drug Study found that the listing of patents after a generic applicant has filed its ANDA led to substantial delay of FDA approval. The report identified two reasons for this delay. First, ''later-issued patents'' often enabled the NDA holder to obtain multiple 30-month stays, resulting in an

[16] In re Buspirone Patent Litig., 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002).

[17] In March 2001, a district court ordered BMS to seek de-listing of the patent. *Mylan Pharms., Inc.* v. *Thompson,* 139 F. Supp. 2d 1 (D.D.C. 2001). The Federal Circuit later reversed this ruling. *Mylan Pharm., Inc.* v. *Thompson,* 268 F.3d 1323, 1329–33 (Fed. Cir. 2001) (holding no private right of action under the Food, Drug, and Cosmetic Act to seek de-listing). By that time, generic buspirone had entered the market, and BMS did not seek to re-list the '365 patent.

[18] The proposed order defines ''Patent Infringement Claim'' to include threats of enforcement and other allegations that an ANDA product infringes the NDA holder's patent.

automatic stay period that significantly exceeds 30 months. BuSpar and Taxol involve allegations relating to improper efforts to obtain such additional stays. Second, later-issued patents also typically presented significant questions whether they met the criteria for listing, and, when courts had ruled, the later-issued patents had been found to be invalid or not infringed.[19] BuSpar, Taxol, and Platinol all are alleged to have involved improper listings. By eliminating the availability of a 30-month stay on later-issued patents, this provision reduces the rewards for obtaining and listing patents improperly. Moreover, by denying BMS the benefit of the 30-month stay on later-issued patents, the proposed order should reduce BMS's incentives to engage in improper behavior before the PTO and the FDA to obtain and list a patent for the purpose of obtaining an unwarranted automatic 30-month stay. This remedy is consistent with the Commission's recommendation to Congress that, to reduce the possibility of abuse of the 30-month stay provision, an ANDA filer only be subject to a 30-month stay for patents listed in the Orange Book prior to the filing of its ANDA.

Paragraph VII also bars a 30-month stay, regardless of when the patent was listed, if BMS engages in certain types of misconduct in connection with obtaining or listing the patent: inequitable conduct before the PTO in obtaining the patent (VII.B); making a false or misleading statement to the FDA in connection with listing the patent (VII.C); or providing information about the patent to the FDA that is inconsistent with information it provided to the PTO (VII.D). These provisions reflect particular types of unlawful conduct charged in the complaint.

Finally, Paragraph VII would also prevent BMS from obtaining a 30-month stay when it has listed a patent that does not claim an approved use of the drug (VII.E) or when the patent is for a metabolite of an active ingredient listed in the NDA (VII.F). These provisions directly respond to the complaint allegations that BMS obstructed generic competition to BuSpar by listing the '365 patent, which did not comply with the standards for listing in the Orange Book. These provisions would not bar BMS from bringing a patent infringement action triggering a 30-month stay if the action is based on a patent claim that is distinct from those identified in these two subparagraphs, and the listing of that distinct additional claim does not conflict with regulations governing Orange Book listings.

To ensure that BMS does not seek to obstruct generic competition through false statements to the FDA outside the Orange Book listing context, such as through the citizen petition process, the proposed order also contains a general prohibition on false statements to the FDA. Paragraph VIII bans false and misleading statements to the FDA that are material to the approvability or sale of a generic version of a BMS brand-name drug product, unless BMS had a reasonable belief that the statement was neither false nor misleading.

To address complaint allegations that BMS engaged in sham litigation, the proposed order's Paragraph IX bars BMS from: asserting any patent infringement claim that is objectively baseless; or seeking to enforce a patent that BMS knows is invalid, unenforceable, or not infringed.

Paragraphs X and XI deal with the acquisition of patents, patent licenses, and conduct in connection with such acquisitions or licenses. These two provisions address complaint allegations that, as one part of its unlawful scheme to delay generic competition to Taxol, BMS entered into an unlawful agreement with ABI that BMS acquire a license to and list an invalid ABI patent in the Orange Book to maintain BMS's monopoly in Taxol.

As in Biovail Corp., FTC Dkt. No. C–4060 (Oct. 2, 2002), the proposed order would require BMS to provide notice to the Commission before it acquires a patent, or an exclusive license to a patent (whether exclusive by its terms or otherwise),[20] if BMS intends to list that patent in the Orange Book. Patents obtained through internal development activities or research joint ventures existing at the time of NDA approval, however, do not present the competitive concerns that the arrangement between BMS and ABI does and are excluded from the proposed order's prior notice requirement.

If BMS acquires a non-exclusive license to a patent, Paragraph XI bars it from participating in enforcement of, licensing of, or setting royalties for, that patent with respect to an ANDA filer. This prohibition applies only to acquisitions that occur after an ANDA referencing the NDA to which the patent relates has been filed. It is intended to ensure that BMS does not attempt to obstruct generic competition by influencing the conduct of the patent holder.

*Provisions Concerning Settlement of Patent Litigation and Other Agreements*

Paragraphs XII though XV address the challenged settlement agreement between BMS and Schein Pharmaceutical, Inc., concerning generic BuSpar. Schein was acquired by Watson Pharmaceuticals in August 2000, and the Commission has determined that under the circumstances here it is not necessary to seek an order against Watson to ensure effective relief.

This aspect of the proposed order would essentially prohibit two categories of conduct:

- Agreements in which the brand-name drug company (the NDA holder) makes payments to a potential generic competitor (an ANDA filer) and the ANDA filer agrees not to market its product for some period of time (except in certain limited circumstances); and
- Agreements between the NDA holder and an ANDA filer in which the generic competitor agrees not to enter the market with a non-infringing generic product, or agrees not to relinquish exclusivity rights.

Paragraph XII of the proposed order covers agreements to resolve patent infringement disputes. It bars agreements wherein (1) the NDA holder makes payments or otherwise transfers something of value to the ANDA filer and (2) the ANDA filer agrees not to market its product for some period of time, subject to two exceptions described below. The ban in Paragraph XII includes not only final settlements of ongoing patent infringement litigation, but also agreements resolving claims of patent infringement that have not resulted in a lawsuit (see definition in Paragraph I.X.). In addition, by virtue of the definition of ''Agreement'' in Paragraph I.G., the proposed order makes it clear that the prohibition on payments for delayed generic entry would cover such arrangements even if they are achieved through separate agreements (for example, when one agreement resolves the patent infringement dispute and another provides for the payment for delayed entry).

The proposed order prohibits not merely cash payments to induce delayed entry, but, more broadly, agreements in which the NDA holder provides something of value to the potential generic entrant, and the ANDA filer agrees in some fashion not to sell

[19] Generic Drug Study at iii–iv, 40, 48–54.

[20] The definition of ''Exclusive License'' in Paragraph I.O includes a license that ''reduces the incentives of the licensor to license the intellectual property to other persons.'' This definition reflects that a license may be nominally non-exclusive, but its terms may be such (for example, when royalties paid to the patent holder would be higher if no generic entry occurs) that the patent holder would have no incentive to license the patent to anyone other than the manufacturer of the brand-name drug to which the patent relates.

its product. Although the pharmaceutical agreements that the Commission has challenged to date have involved cash payments, a company could easily evade a prohibition on such agreements by substituting other things of value for cash payments. Thus, to protect against a recurrent violation, the proposed order is not limited to cash payments.

The proposed order would create two exceptions to Paragraph XII's ban on giving value for delayed entry. First, the ban would not apply if the value BMS provided to the ANDA filer was only: (1) The right to market the ANDA product prior to expiration of the patent that it is alleged to infringe; and/or (2) an amount representing BMS's expected future litigation costs, up to a maximum of two million dollars. This exception reflects that a payment limited to the NDA-holder's expected future litigation costs is not likely to result in a later generic entry date than would be expected to occur absent the payment. As a fencing-in provision, the proposed order sets a two-million dollar limit on expected litigation cost payments. In addition, the exception requires that BMS notify the Commission at least 30 days in advance of consummating such an agreement, to allow an assessment of potential harm to competition that could arise as a result of the exclusivity provisions of the Hatch-Waxman Act. Paragraph XVI sets forth a notification process similar to that used for mergers under the Hart-Scott-Rodino Act, which is designed to permit the Commission to obtain additional information when an agreement's potential effect on the triggering of the 180-day exclusivity period may raise competitive concerns.

A second exception addresses the possibility that there might be some agreements that fall within the terms of the prohibition in Paragraph XII that the Commission would not wish to prohibit. Thus, the proposed order includes a mechanism that would permit the Commission to consider and permit such arrangements.

Paragraph XIII prohibits agreements between an NDA holder and an ANDA filer in which the ANDA filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The complaint alleges that BMS's settlement agreement with Schein not only barred sale of the ANDA product, but also prohibited marketing of any other generic version of BuSpar, regardless of whether it infringed a BMS patent.

The proposed order would also ban agreements in which a first ANDA filer agrees not to relinquish its right to the 180-day exclusivity period provided under Hatch-Waxman (Paragraph XIV). Under a proviso, however, such agreements are permitted in the context of a licensing arrangement if: (1) The first ANDA filer comes to market immediately with a generic version of the reference drug product; (2) the ANDA filer either triggers or relinquishes the 180-day exclusivity period; and (3) BMS complies with the notice requirements of Paragraph XVI. Although a ban on relinquishing exclusivity rights was not part of the challenged settlement agreement between BMS and Schein, such agreements have been used to thwart generic entry and the prohibition of such agreements will help to prevent future unlawful conduct.[21]

Paragraph XV bars agreements that involve payment to an ANDA filer and in which the ANDA filer agrees not to enter the market for a period of time, but the patent infringement litigation continues. As with Paragraph XII's treatment of final settlements, it extends beyond cash payments to cover the NDA holder's providing ''anything of value'' to the ANDA filer. The proposed order also provides for an exception to the provision on interim settlements if BMS presents the agreement to a court in connection with a joint stipulation for a preliminary injunction, and the following conditions are met:

- BMS must provide certain information to the Commission at least 30 days before submitting the joint stipulation to the court, and must also provide certain information to the court along with the joint stipulation;
- BMS may not oppose Commission participation in the court's consideration of the request for preliminary injunction; and
- Either: (1) The court issues a preliminary injunction and the parties' agreement conforms to the court's order; or (2) the Commission determines that the agreement does not raise issues under Section 5 of the FTC Act.

*Notice and Compliance Provisions*

The form and timing of the notice that BMS must provide to the Commission under Paragraphs X, XII, XIV, and XV of the proposed order is set forth in Paragraph XVI. In addition to supplying a copy of the proposed agreement at least 30 days in advance of its consummation, BMS is required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the proposed order requires BMS to identify, among other things, all others known by BMS to have filed an ANDA for a product containing the same chemical entities as the product at issue, as well as the court that is hearing any relevant legal proceedings involving BMS. In addition, BMS must provide the Commission with certain documents that evaluate the proposed agreement.

The proposed order also provides a Hart-Scott-Rodino-type ''second request'' process in connection with the notice required by Paragraph XII.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The proposed order would expire in 10 years.

**Opportunity for Public Comment**

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the agreement. The analysis is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 03–6078 Filed 3–12–03; 8:45 am]

BILLING CODE 6750–01–P

[21] See Abbott Labs., FTC Dkt. No. C–3945 (May 22, 2000); Geneva Pharms, FTC Dkt. No. C–3946 (May 22, 2000); Hoechst Marion Roussel, *et al.*, FTC Dkt. No. D.9293 (May 8, 2001).

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 03F–0088]**

### Ion Beam Applications; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Ion Beam Applications has filed a petition proposing that the food additive regulations be amended by increasing

the maximum permitted energy level of X-rays for treating food to 7.5 million electron volts (MeV) from the currently permitted maximum level of 5.0 MeV.

**FOR FURTHER INFORMATION CONTACT:** Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3423.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 3M4745) has been filed by Ion Beam Applications, 6000 Poplar Ave., suite 426, Memphis, TN. The petition proposes to amend the food additive regulations in § 179.26 *Ionizing radiation for the treatment of food* (21 CFR 179.26) by increasing the maximum permitted energy level of X-rays for treating food to 7.5 MeV from the currently permitted maximum level of 5.0 MeV.

The agency has determined under 21 CFR 25.32(j) 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.

Dated: February 24, 2003.

**Alan M. Rulis,**

*Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.*

[FR Doc. 03–5955 Filed 3–12–03; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 03D–0043]**

### Guidance for Industry on Integration of Dose-Counting Mechanisms into Metered-Dose Inhaler Drug Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Integration of Dose-Counting Mechanisms into MDI Drug Products.'' This guidance is intended to assist manufacturers who are developing or plan to develop drug products for oral inhalation using metered-dose inhalers (MDIs).

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sandy Barnes, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, rm. 8B–45, Rockville, MD 20857, 301–827–1055.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a guidance for industry entitled ''Integration of Dose-Counting Mechanisms into MDI Drug Products.'' This guidance is intended to assist manufacturers who are developing or plan to develop drug products for oral inhalation using MDIs. The guidance reflects the agency's current recommendations regarding the integration of dose-counting mechanisms into MDI drug products for oral inhalation. Although the contents of the guidance should be considered by any manufacturer of any MDI drug product (including nasal MDI products), this guidance is neither specifically intended for manufacturers of already marketed MDI drug products for oral inhalation nor for manufacturers developing MDIs for other routes of administration (e.g., nasal MDIs). It is also not intended for manufacturers developing multidose dry powder inhalers (MDPIs), which already incorporate dose counters as an integral part of the delivery system. Manufacturers developing new MDPIs are encouraged to continue including dose counters in their delivery systems and may find the contents of this guidance useful in their planning.

A draft guidance of the same name was made available for public comment in a notice published in the **Federal Register** of December 11, 2001 (66 FR 64045). This guidance contains only clarifying editorial changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on integrating dose-counting mechanisms into MDI drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: March 5, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03–5956 Filed 3–12–03; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* Council on Graduate Medical Education (COGME).

*Date and Time:* April 10, 2003; 8:30 a.m.—4:30 p.m. April 11, 2003; 8:30 a.m.—12 noon.

*Place:* Holiday Inn Select, Versailles 4, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Status:* The meeting will be open to the public.

*Agenda:* The agenda for April 10 will include: welcome and opening comments

from the Associate Administrator for Health Professions, the Chair of COGME, and the Acting Executive Secretary of COGME. In the morning there will be a panel of speakers on the topics covering the ''Impact of Malpractice Insurance on Physician Practice'' and ''Impact of Residency Duty Hours Restriction—Cost and Structural Adaptations.''

In the afternoon there will be presenters on ''Assessment of Medicare's International Medical Education Payments for Graduate Medical Education.'' After the presentations the Council's three workgroups will convene. They are the Workgroup on Diversity, Workgroup on Graduate Medical Education Financing, and Workgroup on Workforce.

The agenda for April 11 will include a discussion of the Report of the Institute of Medicine, ''Health Professions Education: A Bridge to Quality.'' The three workgroup chairs will give their reports. There will be a discussion on the Development of a Framework for Revised COGME Physician Workforce Goals, plans for future work, and new business.

Agenda items are subject to change as priorities dictate.

**FOR FURTHER INFORMATION CONTACT:** Anyone requiring information regarding the meeting should contact Stanford M. Bastacky, D.M.D., M.H.S.A., Acting Executive Secretary, Council on Graduate Medical Education, Division of Medicine and Dentistry, Bureau of Health Professions, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6326.

Dated: March 7, 2003.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 03–6112 Filed 3–12–03; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* National Advisory Council on Nurse Education and Practice.

*Date and Time:* April 9, 2003, 8:30 a.m.–5 p.m.; April 10, 2003, 8:30 a.m.–3 p.m.

*Place:* The Hotel Washington, Pennsylvania Avenue, NW., at 15th St., Washington, DC 20004.

*Status:* The meeting will be open to the public.

*Agenda:* Department, Agency, Bureau and Division administrative updates. The Council will address issues related to the practice environment of nurses with opening presentation to set the context. Two panels will follow related to the dimensions of the work environment and diversity in the work environment; Council workgroup sessions and discussion of speaker's and panels presentations with development of recommendations related to the practice environment of nurses.

*For Further Information Contact:* Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Ms. Elaine G. Cohen, Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9–35, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–1405.

Dated: March 7, 2003.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 03–6113 Filed 3–12–03; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Eye Institute; 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 Eye Institute Special Emphasis Panel, NEI Conference Grant Review.

*Date:* March 24, 2003.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Jeanette M. Hosseini, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, Bethesda, MD 20892, (301) 451–2020.

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. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5982 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Eye Institute; 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 Eye Institute Special Emphasis Panel, CIGITS and OHTS Cooperative Agreement Applications.

*Date:* April 23, 2003.

*Time:* 11 a.m. to 3 p.m.

*Agenda:* To review and evaluate cooperative agreement applications.

*Place:* Radisson Hotel Old Town, 901 North Fairfax Street, Alexandria, VA 22314.

*Contact Person:* Anne E. Schaffner, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, 6120 Executive Blvd., Suite 350, Bethesda, MD 20892, 301–451–2020.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5985 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health; National Heart, Lung, and Blood Institute; 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 foth 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Small Business Innovative Research.

*Date:* March 19, 2003.

*Time:* 1 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Zoe E Huang, MD, Scientific Review Administrator, Review Branch, Room 7190, eivision of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892–7924, (301) 435–0314.

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. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93,839, Blood Diseases and Resources Research, National Institutes of Health, HHS.)

Dated: March 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5979 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Heart, Lung, and Blood Institute; Notice of 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 a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Advisory Council.

*Date:* May 29, 2003.

*Open:* 8 a.m. to 2 p.m.

*Agenda:* For discussion of program policies and issues.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

*Closed:* 2 p.m. to Adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:*National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Deborah P. Beebe, PhD, Director, Division of Extramural Affairs National Heart, Lung, and Blood Institute, National Institutes of Health, Two Rockledge Center, Room 7100, 6701 Rockledge Center, 7100, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–0260.

Information is also available on the Institute's/Center's Home page: *www.nhlbi.nih.gov/meetings/index.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Disease Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5980 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin 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 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Review of Research Program Project Grants.

*Date:* April 9, 2003.

*Time:* 12:30 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Richard J. Bartlett, PhD., Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5971 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin 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 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Review of Small Grants for New Investigators.

*Date:* April 2–3, 2003.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

*Contact Person:* Richard J. Bartlett, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5972 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institutes of Arthritis and Musculoskeletal and Skin 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 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Review of Research Program Project Grants.

*Date:* March 7, 2003.

*Time:* 8:30 am to 3 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Aftab A. Ansari, PhD, Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594–4952.

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 No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5973 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Arthritis and Musculoskeletal and Skin 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 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, Review of Research Project Grants.

*Date:* March 17, 2003.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Telephone conference call.)

*Contact Person:* Tracy A Shahan, PhD, Scientific Review Administrator, National Institutes of Health, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892. (301) 594–4952.

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. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5976 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–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 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 a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel, Review of RFA–ES–03–002, Environmental Justice (EJ): Partnerships for Communication.

*Date:* April 7–9, 2003.

*Time:* 7 p.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Homewood Suites by Hilton-RDU Airport /RTP, 4603 Central Park Dr., Durham, NC 27703.

*Contact Person:* Leroy Worth, PhD, 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/Room 3171, Research Triangle Park, NC 27709. 919/541–0670. *woth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 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; 93.142, 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, National Institutes of Health, HHS)

Dated: March 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5977 Filed 3–12–03; 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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Intestinal Host Defense.

*Date:* March 27, 2003.

*Time:* 3 p.m. to 4:30 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, Room 754, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–7799, *ls38z@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:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Strategies for Improved Shock Wave Lithotripsy.

*Date:* April 10, 2003.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn, 2650 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Maxine A. Lesniak, PhM, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 756, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–7792, *lesniakm@extra.niddk.nih.gov.*

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Androgen Receptor and Prostate Cancer.

*Date:* April 22–23, 2003.

*Time:* 8 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites Hotel, 1300 Concourse Drive, Linthicum, MD 21090.

*Contact Person:* Dan E. Matsumoto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–6600, (301) 594–8894, *matsumotod@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: March 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5978 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health, National Institute of Neurological Disorders and stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel.

*Date:* March 18, 2003.

*Time:* 2 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:* Raul A. Saavedra, Phd, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301)–496–9223.

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. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: March 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5981 Filed 3–12–03; 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 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 Mental Health Special Emphasis Panel, HIV Prevention in Treatment Settings.

*Date:* March 26, 2003.

*Time:* 8:30 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applicants.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

*Contact Person:* Richard E. Weise, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6140, MSC9606, Bethesda, MD 20892–9606, (301) 443–1225, *rweise@mail.nih.gov.*

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel,

Ancillary Studies to the STAR*D Project—Depression Treatment Variability.

*Date:* April 7, 2003.

*Time:* 1:30 p.m. to 3 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:* Houmam H. Araj, PhD, Scientific review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9608, Bethesda, MD 20892–9608, (301) 443–1340, *haraj@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 Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5983 Filed 3–12–03; 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, Assistive Technology.

*Date:* April 4, 2003.

*Time:* 9 a.m. to 10:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Anne Krey, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Rm. 5E03, Bethesda, MD 20892, (301) 435–6908.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5984 Filed 3–12–03; 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, Pilot Clinical Trials in the Epidemiology, Prevention and Treatment of Respiratory Failure in Children.

*Date:* April 4, 2003.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

*Contact Person:* Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Bldg., Rm. 5B01, Rockville, MD 20852, (301) 435–6889, *bhatnagg@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: March 6, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5986 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious 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 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 Allergy and Infectious Diseases Special Emphasis Panel, Biodefense and Emerging Infectious Disease Opportunities.

*Date:* April 7, 2003.

*Time:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* 6700 B Rockledge Dr., Room 3114, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Alec Ritchie, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAD/NIH/DHHS, 6700 B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–435–1614, *aritchie@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5987 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious 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 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 Allergy and Infectious Diseases Special Emphasis Panel, In Vitro Antiviral Screening Program PART D: Orthopoxviruses and Hemorrhagic Fever.

*Date:* March 27, 2003.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Marriott Washingtonian Center (RIO), 9751 Washingtonian Boulevard, The Board Room, Gaithersburg, MD 20878.

*Contact Person:* Vassil St. Georgiev, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, Room 2102, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–496–2550, *vg8q@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5988 Filed 3–12–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Library of Medicine; Notice of 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 a meeting of the Board of Scientific Counselors, national Library of Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(6), Title 5 U.S.C. as amended. for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Library of Medicine, Board of Scientific Counselors, National Center for Biotechnology Information, National Library of Medicine.

*Date:* April 22, 2003.

*Open:* 9 a.m. to 12 p.m.

*Agenda:* Program Discussion.

*Place:* National Library of Medicine, Building 38, Board Room, 8600 Rockville Pike, Bethesda, MD 20894.

*Closed:* 12 p.m. to 2 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Library of Medicine, Building 28, Board Room, 8600 Rockville Pike, Bethesda, MD 20894.

*Open:* 2 p.m. to 5 p.m.

*Agenda:* Program Discussion.

*Place:* National Library of Medicine, Building 38, Board Room 8600 Rockville Pike, Bethesda, MD 20894.

*Contact Person:* David J. Lipman, MD, Director, Natl Ctr for Biotechnology Information, National Library of Medicine, Department of Health and Human Services, Bethesda, MD 20894.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5974 Filed 3–11–03; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Library of Medicine; Notice of 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 a meeting of the Board of Scientific Counselors, National Library of Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Library of Medicine, Board of Scientific Counselors, Lister Hill Center.

*Date:* May 15–16, 2003.

*Open:* May 15, 2003 9 a.m. to 1 p.m.

*Agenda:* Review of research and development programs and preparation of reports of the Lister Hill National Center for Biomedical Communications.

*Place:* National Library of Medicine, Building 38, Board Room, 2E17, 8600 Rockville Pike, Bethesda, MD 20894.

*Closed:* May 15, 2003, 1 p.m. 2 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Library of Medicine, Building 38, Board Room, 2E17, 8600 Rockville Pike, Bethesda, MD 20894.

*Open:* May 15, 2003 2 p.m. to 5 p.m.

*Agenda:* Review of research and development programs and preparation of

reports of the Lister Hill National Center for Biomedical Communications.

*Place:* National Library of Medicine, Building 38, Board Room, 2E17, 8600 Rockville Pike, Bethesda, MD 20894.

*Open* May 16, 2003, 9 a.m. to 12 p.m

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Library of Medicine, Building 38, Board Room, 2E17, 8600 Rockville Pike, Bethesda, MD 20894.

*Contact Person:* Jackie Duley, Program Assistant, Lister Hill National Center for Biomedical Communications, National Library of Medicine, Bldg 38A, RM 7N–705, Bethesda, MD 301–496–4441.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security. NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: March 5, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5975 Filed 3–12–03; 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, AIDS Behavioral Studies SBIR Applications.

*Date:* March 12, 2003.

*Time:* 8:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Governor's House Hotel, 1615 Rhode Island Avenue, NW, Washington, DC 20036.

*Contact Person:* Ranga V. Srinivas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 435–1167, *srinivar@csr.nih.gov.*

This notice is being published less than 15 days prior to the meting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Review of AIDS Behavioral Studies Member Conflicts.

*Date:* March 12, 2003.

*Time:* 12:30 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Governor's House Hotel, 1615 Rhode Island Avenue, NW, Washington, DC 20036.

*Contact Person:* Ranga V. Srinivas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 435–1167, *srinvar@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:* AIDS and Related Research Integrated Review Group, AIDS and Related Research 6.

*Date:* March 17–18, 2003.

*Time:* 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications and/or proposals.

*Place:* Latham Hotel, 3000 M Street, NW, Washington, DC 20007.

*Contact Person:* Ranga V. Srinivas, PhD, Scientific Review Administrator, Center for Scientific review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435–1167. *srinivar@csr.nih.nov.*

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 Reviews in Mental Disorders.

*Date:* March 17, 2003.

*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:* Mary Sue Krause, MED, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848. Bethesda, MD 20892, (301) 435–0902, *krausem@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, ZRG1 VACC 01: Infectious Disease Vaccines.

*Date:* March 17–18, 2003.

*Time:* 2 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Mary Clare Walker, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 7852, Bethesda, MD 20892, (301) 435–1165.

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, Cognition and Language.

*Date:* March 18, 2003.

*Time:* 4 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:* Cheri Wiggs, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3180, MSC 7848, Bethesda, MD 20892, (301) 435–1261.

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, Genomics and Bioengineering.

*Date:* March 20, 2003.

*Time:* 9 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* American Inn of Bethesda, 8130 Wisconsin Ave., Bethesda, MD 20814.

*Contact Person:* David J. Remondini, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6154, MSC 7890, Bethesda, MD 20892, (301) 435–1038, *djr@helix,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, Learning and Memory; Cellular and Molecular Mechanisms.

*Date:* March 20, 2003.

*Time:* 12 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:* John Bishop, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, (301) 435–1250.

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, Drug Prevention and Smoking Cessation.

*Date:* March 21, 2003.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

*Contact Person:* Karen Sirocco, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, (301) 435–0676, *siroccok@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, ZRG1 PBC(3) MIMS Resource Review.

*Date:* March 23–25, 2003.

*Time:* 5 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel at Massachusetts Institute of Technology, 20 Sidney Street, Boston, MA 02139.

*Contact Person:* Zakir Bengali, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5150, MSC 7842, Bethesda, MD 20892, (301) 435–1742.

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:* AIDS and Related Research Integrated Review Group; AIDS and Related Research 1.

*Date:* March 24–25, 2003.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Latham Hotel, 3000 M Street, NW., Washington, DC 20007.

*Contact Person:* Kenneth Roebuck, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@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, Computational Neuroscience.

*Date:* March 24, 2003.

*Time:* 11 a.m. to 1 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 Bishop, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, (301) 435–1250.

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 Reviews in Treatment of Depression.

*Date:* March 24, 2003.

*Time:* 1 p.m. to 2 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:* Mary Sue Krause, MED, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 435–0902, *krausem@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, Diagnosis of Mental Disorders.

*Date:* March 24, 2003.

*Time:* 2:30 p.m. to 4:30 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:* Mary Sue Krause, MED, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, 301–435–0902, *krausem@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, ZRG1–DMG 90S: Diagnostic Imaging.

*Date:* March 25, 2003.

*Time:* 2 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:* Lee Rosen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, MDCN Fellowship Review Group A—Development, Synaptic Plasticity and Neurodegeneration.

*Date:* March 26–27, 2003.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

*Contact Person:* Joanne T Fujii, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5204, MSC 7850, Bethesda, MD 20892, (301) 435–1178, *fujiij@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG MBC–1 (29) DBBD F 31 SEP.

*Date:* March 26–27, 2003.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

*Contact Person:* Neal B. West, PhD, Program Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892–7808, 301–435–2514, *westnea@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Polyoma Transformation.

*Date:* March 26, 2003.

*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:* Michael R. Schaefer, PhD, Scientific Review Administrator, Genetic Sciences IRG, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6166, MSC 7890, Bethesda, MD 20892, (301) 435–2477, *schaefem@csr.nih.gov.*?≤

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Polyoma Transformation.

*Date:* March 26, 2003.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Jean Hickman, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4194, MSC 7808, Bethesda, MD 20892, (301) 435–1146.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Biochemical Pharmacology fo Alcohol.

*Date:* March 26, 2003.

*Time:* 2 p.m. to 4:30 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:* Gamil C Debgas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7844, Bethesda, MD 20892, (301) 435–1247, *eskayr@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Physics.

*Date:* March 26, 2003.

*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:* Paul K. Strudler, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186, MSC 7804, Bethesda, MD 20892, (301) 435–1716, *strudlep@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, SNEM 1 Member Conflict: Community Level Health Promotion.

*Date:* March 26, 2003.

*Time:* 4 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:* Gerturde K. McFarland, DNSC, FAAN, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, (301) 435–1784, *mcfarlag@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG1 SRB 51R:PAR 01–101: In Vivo Imaging Technology: Phased Innovation AWD.

*Date:* March 27, 2003.

*Time:* 8 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

*Contact Person:* Eileen W Bradley, DSC, Chief and Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG1 SSS2 (10B) Proteomics, Protein Expression, and Protein Therapeutics.

*Date:* March 27–28, 2003.

*Time:* 8:30 a.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Ave, Chevy Chase, MD 20815.

*Contact Person:* Prabha L. Atreya, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7842, Bethesda, MD 20892, (301) 435–8367, *atreyape@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Diagnosis and Treatment of Cancer.

*Date:* March 27–28, 2003.

*Time:* 8:30 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

*Contact Person:* Shen K. Yang, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, MSC 7804, Bethesda, MD 20892, (301) 435–1213, *yangsh@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG1 PTHB 03 M:.

*Date:* March 27, 2003.

*Time:* 1 p.m. to 3p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Martin L. Padarathsingh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6212, MSC 7804, Bethesda, MD 20892, (301) 435–1717.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Genomics.

*Date:* March 27, 2003.

*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:* Camilla E. Day, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435–1037, *dayc@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Behavioral Genetics and Mental Health (SNEM 2 Members).

*Date:* March 27, 2003.

*Time:* 2:15 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, 3158–F, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Ann Hardy, DRPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, (301) 435–0695, *hardyan@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG1 SRB 54R:PAR01–101: In Vivo Imaging Technology: Member Conflict.

*Date:* March 27, 2003.

*Time:* 3 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda MD 20814.

*Contact Person:* Eileen W Bradley, DSC, Chief and Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG1 SRB 53R:PAR01–101: In Vivo Imaging Technology: Member Conflict.

*Date:* March 27, 2003.

*Time:* 4:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

*Contact Person:* Eileen W Bradley, DSC, Chief and Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Leukemia Virus.

*Date:* March 27, 2003.

*Time:* 5 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:* Angela Y. Ng, PhD, MBA, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6200, MSC 7804, (For courier delivery, use MD 20817), Bethesda, MD 20892, 301–435–1715, *nga@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, ZRG1 SRB 52R:PAR01–102: In Vivo Imaging Technology:SBIR/STTR.

*Date:* March 28, 2003.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

*Contact Person:* Eileen W Bradley, DSC, Chief and Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, (301) 435–1179, *bradleye@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Models of Carcinogenecis and Prevention.

*Date:* March 28, 2003.

*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:* Elaine Sierra-Rivera, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Behavioral Neuroendocrinology.

*Date:* March 28, 2003.

*Time:* 2 p.m. to 4:30 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:* Gamil C Debbas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7844, Bethesda, MD 20892, (301) 435–1247, *eskay@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Nutritional Metabolism.

*Date:* March 28, 2003.

*Time:* 12 p.m. to 2 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:* Dennis Leszczynski, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, (301) 435–1044.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Chemical Senses: Olfaction.

*Date:* March 31, 2003.

*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:* John Bishop, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5180, MSC 7844, Bethesda, MD 20892, (301) 435–1250.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Reviews in Behavioral Pharmacology and Addiction.

*Date:* March 31, 2003.

*Time:* 2 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:* Mary Sue Krause, MED, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, 301–435–0902, *krausem@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 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: March 5, 2003

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 03–5989 Filed 3–12–03; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## Notice of Receipt of Applications for Renewal for Endangered Species Permit

**AGENCY:** U.S. Fish and Wildlife Service, Department of the Interior.

**ACTION:** Notice of receipt.

**SUMMARY:** The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*):

**PRT–697823**

*Applicant:* Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, Hadley, Massachusetts

**DATES:** Written data or comments on this application must be received at the address given below by April 14, 2003.

**ADDRESSES:** Documents and other information submitted with this application are available for review by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035. Attention: Diane Lynch, Regional Endangered Species Permits Coordinator. Telephone: (413) 253–8628; Facsimile: (413) 253–8482.

**FOR FURTHER INFORMATION CONTACT:** Diane Lynch, Telephone: (413) 253–8628; Facsimile: (413) 253–8482.

**SUPPLEMENTARY INFORMATION:** You are invited to comment on the application from the Assistant Regional Director, Ecological Services, PRT–TE697823. This applicant requests renewal of their current permit for take activities for all listed species in the states of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, West Virginia and the District of Columbia for the purpose of scientific research and enhancement of propagation or survival of the species as prescribed by U.S. Fish and Wildlife Service recovery documents.

Dated: February 26, 2003.

**Richard O. Bennett,**

*Acting Regional Director.*

[FR Doc. 03–6041 Filed 3–12–03; 8:45 am]

**BILLING CODE 4310–55–M**

## DEPARTMENT OF THE INTERIOR

## Bureau of Indian Affairs

## Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians Liquor Control Code

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice publishes the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians Liquor Control Code. The Code regulates the sale, possession and use of alcoholic liquor on the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians (Tribes') Reservation and other lands subject to tribal jurisdiction, in conformity with the laws of the State of Oregon, where applicable and necessary. Although the Code was adopted on December 9, 2001, it does not become effective until published in the **Federal Register** because the failure to comply with the Code may result in criminal charges.

**EFFECTIVE DATE:** This Code is effective March 13, 2003.

**FOR FURTHER INFORMATION CONTACT:** Duane Bird Bear, Office of Tribal Services, Branch of Tribal Relations, 1951 Constitution Avenue, NW., MS–320–SIB, Washington, DC 20240–0001; Telephone (202) 513–7641.

**SUPPLEMENTARY INFORMATION:** Under the Act of August 15, 1953, Public Law 83–277, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner,* 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of the adopted liquor ordinances for the purpose of regulating liquor transactions in Indian Country. The Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians Liquor Code, Resolution No. 01–091, was duly adopted by the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians Tribal Council on December 9, 2001. The Tribes wish to establish uniform policies to assure a high-quality workforce, ensure the protection of employee rights and set forth the expectations of all employees and managers in conducting employee relations matters.

This notice is published in accordance with the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 Department Manual 8.1.

I certify that by Resolution No. 01–091, the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians Liquor Control Code was duly adopted by the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians Tribal Council on December 9, 2001.

Dated: February 26, 2003.

**Aurene M. Martin,**

*Acting Assistant Secretary—Indian Affairs.*

The Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians Liquor Control Code, Resolution No. 01–091, reads as follows:

**Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians Liquor Control Code Title 5—Regulatory Provisions Chapter 5–1 Liquor Control**

*5–1–1 Authority and Purpose*

(a) The authority for this Code and its adoption by Tribal Council is found in the Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians Tribal Constitution under Article I—section 1, Article VI—section 2 and the Act of October 17, 1984, Public Law 98–481, 98 Stat. 2250.

(b) This Code is for the purpose of regulating the sale, possession and use of alcoholic liquor on the Confederated Tribes of Coos, Lower Umpqua and Siuslaw Indians (Tribes') Reservation and other lands subject to tribal jurisdiction.

*5–1–2 Definitions*

To the extent that definitions are consistent with tribal or federal law, terms used herein shall have the same meaning as defined in Oregon Revised Statutes Chapter 471 and in Oregon Administrative Rules Chapter 845.

(a) *Alcoholic Liquor* shall mean any alcoholic beverage containing more than one-half of 1 percent alcohol by volume, and every liquid or solid, patented or not, containing alcohol and capable of being consumed by a human being.

(b) *Tribes' Reservation* shall mean all lands held in trust by the United States for the Tribes or their members and all lands owned by the Tribes, wherever located.

(c) *Sell or To Sell* refer to anything forbidden by this Chapter and related to alcoholic liquor, they include:

(1) To solicit or receive an order.

(2) To keep or expose for sale.

(3) To deliver for value or in any way other than purely gratuitously.

(4) To peddle.

(5) To keep with intent to sell.

(6) To traffic in.

(7) For any consideration, promise or obtained directly or indirectly under any pretext or by any means or procure or allow to be procured for any other person.

(d) *Sale* includes every act of selling as defined in paragraph (c) of this section.

*5–1–3 Prohibited Activity*

(a) It shall be unlawful for any person to sell, trade or manufacture any alcoholic liquor on the Tribes' Reservation except as provided in this Code.

(b) It shall be unlawful for any business establishment or person on the Tribes' Reservation to possess, transport or keep with intent to sell, barter or trade to another any liquor, except for those commercial liquor establishments on the Tribes' Reservation licensed by the Tribes, provided, however, that a person may transport liquor from a licensed establishment consistent with the terms of the license.

(c) It shall be unlawful for any person to consume alcoholic liquor on a public highway.

(d) It shall be unlawful for any person to publicly consume any alcoholic liquor at any community function, or at or near any place of business, Indian celebration grounds, recreational areas, including ballparks and public camping areas, the Tribal Headquarters area and any other area where minors gather for meetings or recreation, except within a tribally licensed establishment where alcohol is sold.

(e) It shall be unlawful for any person under the age of 21 years to buy, attempt to buy or to misrepresent their age in attempting to buy, alcoholic liquor. It shall be unlawful for any person under the age of 21 years to transport, possess or consume any alcoholic liquor on the Tribes' Reservation, or to be under the influence of alcohol or to be at an established commercial liquor establishment, except as authorized under section 5–1–5 of this Code. No person shall sell or furnish alcoholic liquor to any minor.

(f) Alcoholic liquor may not be given as a prize, premium or consideration for a lottery, contest, game of chance or skill, or competition of any kind.

*5–1–4 Procedure for License*

(a) Any request for a license under this Code must be presented to the Tribal Council at least 30 days prior to the requested effective date. The Tribal Council shall set license conditions at least as strictly as those required by federal law, including at a minimum:

(1) Liquor may only be served and handled in a manner no less strict than allowed under Oregon Revised Statutes chapter 471.

(2) Liquor may only be served by staff of the licensee; and

(3) Liquor may only be served in rooms where gambling is not taking place.

(b) Council action on a license request must be taken at a regular or special meeting. Unless the request is for a special event license, the Council shall give at least 14 days' notice of the meeting at which the request will be considered. Notice shall be posted at the Tribal Council offices and at the establishment requesting the license, and will be sent by Certified Mail to the Oregon Liquor Control Commission.

*5–1–5 Sale or Service of Liquor by Licensee's Minor Employees*

(a) The holder of a license issued under this Code or Oregon Revised Statutes chapter 472 may employ persons 18, 19 and 20 years of age who may take orders for, serve and sell alcoholic liquor in any part of the licensed premises when that activity is incidental to the serving of food except in those areas classified by the Oregon Liquor Control Commission as being prohibited to the use of minors. However, no person who is 18, 19 or 20 years of age shall be permitted to mix, pour or draw alcoholic liquor except when pouring is done as a service to the patron at the patron's table or drawing is done in a portion of the premises not prohibited to minors.

(b) Except as stated in this section, it shall be unlawful to hire any person to work in connection with the sale and service of alcoholic beverages in a tribally licensed liquor establishment if such person is under the age of 21 years.

*5–1–6 Warning Signs Required*

(a) Any person in possession of a valid retail liquor license, who sells liquor by the drink for consumption on the premises or sells for consumption off the premises, shall post a sign informing the public of the effects and risks of alcohol consumption during pregnancy.

(b) The sign shall:

(1) Contain the message: ''Pregnancy and alcohol do not mix. Drinking alcoholic beverages, including wine, coolers and beer, during pregnancy can cause birth defects.''

(2) Be either:

(A) A large sign, no smaller than 8½ by 11 inches in size with lettering no smaller than five-eighth of an inch in height; or

(B) A reduced sign, 5 by 7 inches in size with lettering of the same proportion as the large sign described in paragraph (A) of this subsection.

(3) Contain a graphic depiction of the message to assist nonreaders in understanding the message. The depiction of a pregnant female shall be universal and shall not reflect a specific race or culture.

(4) Be in English unless a significant number of the patrons of the retail premises use a language other than English as a primary language. In such cases, the sign shall be worded both in English and the primary language or languages of the patrons.

(5) Be displayed on the premises of all licensed retail liquor premises as either a large sign at the point of entry, or a reduced sized sign at points of sale.

(c) The person described in paragraph (a) of this section shall also post signs of any size at places where alcoholic beverages are displayed.

*5–1–7 Civil Penalty*

(a) Any person who violates the provisions of this Code is deemed to have consented to the jurisdiction of the Tribal Court and may be subject to a civil penalty in Tribal Court for a civil infraction. Such civil penalty shall not exceed the sum of one thousand dollars ($1,000) for each such infraction, provided, however, that the penalty shall not exceed five thousand dollars ($5,000) if it involves minors.

(b) The procedures governing the adjudication in Tribal Court of such civil infractions shall be those set out in the Trial Court rules.

(c) The Tribal Council hereby specifically finds that such civil penalties are reasonably necessary and are related to the expense of governmental administration necessary in maintaining law and order and public safety on the Reservation and in managing, protecting and developing the natural resources on the Reservation. It is the legislative intent of the Tribal Council that all violations of this Chapter, whether committed by tribal members, non-member Indians or non-Indians, be considered civil in nature rather than criminal.

*5–1–8 Severability*

If a court of competent jurisdiction finds any provision of this Code to be invalid or illegal under applicable Federal or Tribal law, such provision shall be severed from this Code and the remainder of this Code shall remain in full force and effect.

*5–1–9 Consistency With State Law*

The Tribes agree to perform in the same manner as any other Oregon business entity for the purpose of liquor licensing and regulations, including but not limited to licensing, compliance with the regulations of the Oregon Liquor Control Commission, maintenance of liquor liability insurance, which is incorporated as it is specifically set forth herein, as it may be amended from time to time.

*5–1–10 Effective Date*

This Code shall be effective upon publication in the **Federal Register** after approval by the Secretary of the Interior or his designee.

[FR Doc. 03–6114 Filed 3–12–03; 8:45 am]

BILLING CODE 4310–4J–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[WY–100–03–1310–DB]**

### Notice of Intent To Prepare an Environmental Impact Statement and Provide Notice of Public Meeting, Jonah Infill Drilling Project, Sublette County, WY, and Notice of the Potential for Amendment of the Pinedale Resource Management Plan

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) and to conduct public scoping for the Jonah Infill Drilling Project, Sublette County, Wyoming, and Notice of the Potential for Amendment of the Pinedale Resource Management Plan.

**SUMMARY:** EnCana Oil and Gas (USA) Inc., BP America, and other natural gas development companies (hereinafter referred to as ''the Operators'') have submitted to the Bureau of Land Management (BLM) a proposal to expand natural gas exploration and development operations. The Jonah Infill Drilling Project is located in an area known as the Jonah Field, in Sublette County, Wyoming. Under the provisions of section 102(2)(C) of the National Environmental Policy Act (NEPA), the BLM announces its intentions to prepare an EIS and to solicit public comments regarding issues and resource information. Based on the information developed during the course of this analysis, the BLM may decide it is necessary to amend the 1988 Pinedale Resource Management Plan (RMP).

**DATES:** This notice initiates the public scoping process. The BLM can best use public input if comments and resource information are submitted within 45 days of the Publication of Environmental Protection Agency's (EPA) notice in the **Federal Register.** A Scoping Notice will be distributed by mail on or about the date of the publication of this notice. Information and a copy of the Scoping Notice may be obtained by writing, or visiting, the BLM Pinedale Field Office, address listed below.

The BLM will host a public meeting within 30 days of the publication of this notice. Information regarding date, time, and location of the meeting will be available from the Pinedale Field Office and posted on its Web site listed at the end of this Notice. All comments received at the public meeting, submitted in writing by mail, or e-mail will aid the BLM in identifying issues, developing a range of alternatives, and analyzing environmental impacts.

**ADDRESSES:** Address questions and comments to the Pinedale Field Office, PO Box 768, Pinedale, Wyoming 82941, phone number 307–367–5300, or send them electronically to *pinedale_wymail@blm.gov.* Information and a copy of the Scoping Notice for the Jonah Infill Drilling Project EIS may be obtained by writing or visiting the BLM Pinedale field office. The scoping notice will also be posted on the Wyoming BLM NEPA Web site, *http://www.wy.blm.gov/nepa/nepadocs.htm.* Written comments may be sent, or hand-delivered, to the BLM Pinedale Field Office, 432 East Mill Street, PO Box 768, Pinedale, WY 82941.

Your response is important and will be considered in the environmental analysis process. If you do respond, we will keep you informed of decisions resulting from this analysis. Please note that public comments and information submitted regarding this project including names, e-mail addresses, and street addresses of the respondents will be available for public review and disclosure at the above address during regular business hours (7:45 a.m. to 4:30 p.m.) Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish to withhold your name, email address, or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by the law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

**FOR FURTHER INFORMATION CONTACT:** Eldon Allison, Project Manager, BLM, Pinedale Field Office, PO Box 768, Pinedale, Wyoming 82941, telephone 307–367–5300.

**SUPPLEMENTARY INFORMATION:** The Jonah Infill Drilling Project (JIDP) area is located in south-central Sublette County approximately 32 miles southeast of Pinedale, and 28 miles northwest of Farson, Wyoming. Drilling is proposed in Townships 28 and 29 North, Ranges 107 through 109 West, 6th Principal Meridian.

The operators have submitted to the BLM a proposal to expand exploration and development of natural gas resources in the Jonah Field area, spanning a period of about 25 years. The

total project area is approximately 30,200 acres. This acreage includes approximately 28,280 acres of Federal surface and mineral estate managed by BLM; 1,280 acres of State of Wyoming surface and minerals; and 640 acres of private surface ownership. All of the privately owned surface acres are split estate (private surface/Federal minerals) lands.

The operators' original proposal to drill 450 wells in addition to 47 existing wells at the same number of locations was approved by the BLM in the Environmental Assessment, Finding of No Significant Impact and Decision Record for the Modified Jonah Field II Natural Gas Project, March 2000 (Modified Jonah Field II EA). The operators now propose to drill 1,250 additional wells from 850 well locations within the same area analyzed in the Modified Jonah Field II EA. The operators' new proposal is based on a 10 to 20 acre down-hole spacing pattern (32 to 64 wells per aliquot section). The operators propose to explore known productive formations as well as deeper formations that have not been tested. The planned development would include the following associated structures and facilities in addition to the 850 proposed new well locations: needed separators and hydrators, storage tanks, field access and resource roads, a system of gathering and sales pipelines, compressor stations, and five additional water wells.

During the preparation of the EIS, proposed development of additional exploratory wells within the project area on public lands may be approved subject to an environmental review by BLM and to a finding that such development is consistent with the 1988 Pinedale Resource Management Plan (RMP). Such a review will also ensure that the proposed development would not limit the consideration of a range of reasonable alternatives for this proposed Jonah Infill Drilling Project EIS.

The purpose of this project is to extract and recover natural gas from the Jonah Field by allowing the operators to provide clean burning fuel for distribution to consumers. In addition, this project would meet the goals and objectives of the President's National Energy Plan by diversifying domestic energy supplies, improving and accelerating environmental protection, and strengthening America's energy security.

BLM personnel, other agencies, and individuals have preliminarily identified the following issues that will be addressed in the EIS: Air quality; Federally-listed Threatened, Endangered, Candidate and Sensitive Species and their habitats; surface and groundwater resources; short-term revegetation and restoration of disturbed areas and their long-term stabilization, including control of noxious weeds; prehistoric and historic cultural resources; social and economic effects to the local communities; wildlife habitat and fisheries; nesting raptors; wetlands and riparian areas; visual and landscape resources; and recreation activities and opportunities, such as hunting and fishing.

The BLM has identified the following benefits that may be derived from the natural gas development: Increased royalties and tax revenues to local, State, and Federal governments; additional opportunities for employment and economic benefits for communities near the project area; increases in Wyoming's share of new and existing natural gas markets; and development of natural gas resources to assist in attainment of clean air objectives in conformance with Presidential and Congressional directives.

Any authorizations and actions proposed for approval in the EIS will be evaluated to determine if they conform to the decisions in the 1988 Pinedale RMP. Actions that result in a change in the scope of resource uses, terms and conditions, and decisions of the Pinedale RMP may require amendment of the RMP. If the BLM determines that a plan amendment is necessary, preparation of the JIDP EIS and the analysis necessary for the RMP amendment may occur simultaneously. Appropriate analysis will accompany the decision to conduct an RMP amendment.

Also, the Pinedale RMP is currently being revised, with completion scheduled for October 2004. Because the Jonah Infill Drilling Project EIS and the Pinedale RMP revision will be developed on overlapping schedules, the information and analysis needed for these planning efforts will be jointly prepared and used for both EISs, to the greatest extent possible. Further information of the status of this RMP revision may be obtained from the Web site at *http://www.pinedalermp.com.*

The BLM will announce public meetings and comment periods through local news media and the Pinedale Field Office Web site, *http://www.wy.blm.gov/pfo/info.htm,* at least 15 days prior to the event. The first in a series of meetings is tentatively scheduled for late March 2003, in Pinedale, Wyoming. The BLM will also provide additional opportunities for public participation throughout the preparation of the EIS.

Dated: February 13, 2003.

**Robert A. Bennett,**

*State Director.*

[FR Doc. 03–6084 Filed 3–12–03; 8:45 am]

BILLING CODE 4310–22–P

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## DEPARTMENT OF THE INTERIOR

## Bureau of Land Management

**[WY–030–1310–DB]**

## Notice of Intent To Prepare an Environmental Impact Statement and Conduct Scoping for the Seminoe Road Coalbed Methane Natural Gas Development Project, Carbon County, Wyoming, and Notice of the Potential for Amendment of the Great Divide Resource Management Plan

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) and to conduct scoping for the Seminoe Road Gas Development Project, Carbon County, Wyoming, and Notice of the Potential for Amendment of the Great Divide Resource Management Plan (RMP).

**SUMMARY:** Under section 102(2)(C) of the National Environmental Policy Act (NEPA) of 1969, as amended, the Bureau of Land Management (BLM), Rawlins Field Office, announces its intent to prepare an EIS on the potential impacts of a proposed coalbed methane natural gas development project. In September 2002, the BLM received from Dudley & Associates, LLC (Dudley) a proposal to drill and develop up to 1,240 wells (on an estimated 785 well pad sites) and associated facilities. The proposed project area encompasses approximately 137,000 acres of mixed Federal, State, and private land. A 30 to 40 year development and operational period is proposed. The project area is located approximately 20 air miles northeast of the city of Rawlins, Carbon County, Wyoming. Based on the information developed during the course of this analysis, the BLM may decide it is necessary to amend the 1990 Great Divide RMP.

**DATES:** This notice initiates the public scoping process. The BLM can best use public input if comments and resources information are submitted within 60 days of the publication of this notice in the **Federal Register**. Public scoping meetings will be held in Rawlins, WY and Hanna, WY. The BLM will notify the public of meeting dates, times, and locations 15 days in advance by a news release to the media, individual letter

mailings, and posting on the BLM Web site listed below.

**ADDRESSES:** Address questions and comments to the Bureau of Land Management, Rawlins Field Office, David Simons, Team Leader, 1300 North Third Street, PO Box 2407, Rawlins, Wyoming 82301, telephone (307) 328–4200, or send them electronically to *rawlins_wymail@blm.gov.* Additionally, the scoping notice will be posted on the Wyoming BLM National Environmental Policy Act (NEPA) Web page at *http://www.wy.blm.gov/nepa/nepadocs.htm.* Your response is important and will be considered in the environmental analysis process. If you do respond, we will keep you informed of decisions resulting from this analysis. Please note that public comments and information submitted regarding this project including names, e-mail addresses, and street addresses of the respondents will be available for public review and disclosure at the above address during regular business hours (7:45 a.m. to 4:30 p.m.) Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish to withhold your name, email address, or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by the law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, David Simons, Project Manager, 1300 North Third Street, PO Box 2407, Rawlins, Wyoming 82301, phone (307) 328–4200, email address: *rawlins_wymail@blm.gov.*

**SUPPLEMENTARY INFORMATION:** The Seminoe Road Gas Development Project is located in Townships 21, 22, 23, and 24 North, Ranges 84, 85 and 86 West, Sixth Principal Meridian, Carbon County, Wyoming. The project area is located approximately 20 air miles northeast of Rawlins and approximately 15 air miles northeast of Sinclair, Wyoming east of Carbon County Road 351 (Seminoe Road). The project area covers approximately 137,000 acres of Federal (49 percent) and private (49 percent) surface with a small amount of State land (<2 percent). The BLM Rawlins Field Office manages the Federal surface lands and the Federal mineral estate.

In September 2002, Dudley & Associates LLC (Dudley) submitted a proposal to drill and develop potentially up to 1,240 coalbed methane natural gas wells on up to 785 locations. Associated project facilities would include roads, well pads, gas and water collection pipelines, compressor stations, water disposal systems, and a power supply system. During the preparation of the EIS, proposed development within the project area on public lands may be approved subject to an environmental review by BLM and to a finding that such development is consistent with the 1990 Great Divide Resource Management Plan (RMP). Such a review will also ensure that the proposed development would not limit the consideration of a range of reasonable alternatives for this proposed Seminoe Road Gas Development Project EIS.

Any authorizations and actions proposed for approval in the EIS will be evaluated to determine if they conform to the decisions in the 1990 Great Divide RMP. Actions that result in a change in the scope of resource uses, terms and conditions, and decisions of the approved Great Divide RMP may require amendment of the RMP. If the BLM determines that a plan amendment is necessary, preparation of the Seminoe Road Coalbed Methane Natural Gas Development Project EIS and the analysis necessary for the amendment may occur simultaneously. Appropriate analysis will accompany the decision to conduct an RMP amendment.

Development of coalbed methane natural gas development from the Seminoe Road area will provide additional supplies of this clean-burning fuel to consumers. This project meets the goals and objectives of the President's National Energy Plan by diversifying domestic energy supplies, improving and accelerating environmental protection, and strengthening the Nation's energy security.

The EIS will address cumulative impacts and include consideration of the effects of the projects addressed in both the EA for the Seminoe Road Coalbed Methane Pilot Project (WY–030–EA00–288) and the EA for the Seminoe Road Natural Gas Gathering Pipeline Access Road and Compressor Station Storage Yard Access Road Project (WY–030–EA2–229). Potential issues to be addressed in the EIS include but are not limited to: Surface and ground water resources, air quality, wildlife populations and their habitats, private and public land access concerns, road development and transportation, reclamation, noxious weed control, reclamation, conflicts with livestock grazing operations, protection of potential cultural and paleontological resources, threatened and endangered wildlife and plant species, and socioeconomic impacts.

The project area is managed under the Great Divide RMP (1990). This RMP is currently being revised under the title of Rawlins RMP, with completion scheduled for October 2004. Because the Seminoe Road Gas Development Project EIS and the Rawlins RMP revision will be developed on overlapping schedules, the information and analysis needed for these planning efforts will be jointly prepared and used for both EISs, to the greatest extent possible. Further information of the status of this RMP revision may be obtained from the Web site at *http://www.rawlinsrmp.com.*

Dated: February 12, 2003.

**Donald A. Simpson,**

*Acting State Director.*

[FR Doc. 03–6085 Filed 3–12–03; 8:45 am]

**BILLING CODE 4310–22–P**

## INTERNATIONAL TRADE COMMISSION

**[USITC SE–03–009]**

### Sunshine Act Meeting

*Agency Holding the Meeting:*
International Trade Commission.
*Time and Date:*
March 24, 2003, at 2 p.m.
*Place:*
Room 101, 500 E Street, SW., Washington, DC 20436.
*Telephone:*
(202) 205–2000.
*Status:*
Open to the public.
*Matters to be Considered:*

1. Agenda for future meetings: none.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 731–TA–1006, 1008, and 1009 (Final)(Urea Ammonium Nitrate Solutions from Belarus, Russia, and Ukraine)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before April 3, 2003.)
5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: March 11, 2003.

By order of the Commission.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. 03–6219 Filed 3–11–03; 2:42 pm]

BILLING CODE 7020–02–P

## DEPARTMENT OF JUSTICE

### Civil Division; Agency Information Collection Activities: Proposed Collection; Comments Requested

**ACTION:** 60-Day emergency notice of information collection under review: Annuity Broker Qualification Declaration Form.

The Department of Justice, Civil Division has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with emergency review procedures of the Paperwork Reduction Act of 1995. OMB approval has been requested by March 14, 2003. The proposed information collection is published to obtain comments from the public and affected agencies. If granted, the emergency approval is only valid for 180 days. Comments should be directed to OMB, Office of Information and Regulation Affairs, Attention: Department of Justice Desk Officer (202) 395–6466, Washington, DC 20503.

During the first 60 days of this same review period, a regular review of this information collection is also being undertaken. All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Kenneth L. Zwick, Director, Office of Management Programs, Civil Division, U.S. Department of Justice, Main Building, Room 3140, 950 Pennsylvania Avenue NW., Washington, DC 20530, or facsimile (202) 514–8071.

Request written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agencies 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 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:*

(1) *Type of information collection:* This is a new collection.

(2) *The title of the form/collection:* Annuity Broker Qualification Declaration Form.

(3) *The agency form number, if any, and the applicable component of the department sponsoring the collection: Form Number:* none. Civil Division, Torts Branch, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Annuity Brokers. Other: None. The information collection requirement contained in this rule will be used to determine whether a broker meets the minimum qualifications to be listed as an annuity broker pursuant to section 11015(b) of Public Law 107–273.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 400 respondents will complete the application in approximately 1 hour per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total public burden associated with this application is 400 hours.

If additional information is required contact: Robert B. Briggs, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, United States Department of Justice, 601 D Street NW., Patrick Henry Building, Suite 1600, NW., Washington, DC 20530.

Dated: March 10, 2003.

**Robert B. Briggs,**

*Department Clearance Officer, Department of Justice.*

[FR Doc. 03–6080 Filed 3–12–03; 8:45 am]

BILLING CODE 4410–12–M

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances; Notice of Registration

By notice dated October 25, 2002, and published in the **Federal Register** on November 7, 2002, (67 FR 67869), Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of methamphetamine (1105), a basic class of controlled substance list in Schedule II.

The firm plans to import the listed controlled substance to bulk manufacture controlled substances.

No comments or objections have been received regarding this controlled substance. DEA has considered the factors in Title 21, United States Code, section 823(a) and determined that the registration of Chattem Chemicals, Inc., is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Chattem Chemicals, Inc. on a regular basis to ensure the company's continued registration is consistent with the public interest. The investigation included inspection and testing of the company's physical security system, audit of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history.

Therefore, pursuant to section 1008(a) of the Controlled Substances Import and Export Act and in accordance with Title 21 Code of Federal Regulations, § 1301.34, the above firm is granted registration as an importer of the basic class of controlled substance listed above.

Dated: February 28, 2003.

**Laura M. Nagel,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 03–6066 Filed 3–12–03; 8:45 am]

BILLING CODE 4410–09–M

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Richard J. Clement, M.D.; Revocation of Registration

On November 19, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Richard J. Clement, M.D. (Dr. Clement) of Lake Charles, Louisiana, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration AC3534814 under 21 U.S.C. 824(a), and deny any

pending applications for renewal of that registration pursuant to 21 U.S.C. 823(f). As a basis for revocation, the Order to Show Cause alleged that Dr. Clement is not currently authorized to practice medicine or handle controlled substances in the State of Louisiana, the state in which he practices. The order also notified Dr. Clement that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Dr. Clement at his registered location in Lake Charles, Louisiana. DEA subsequently received a signed receipt notification indicating that the Order to Show Cause was received on behalf of Dr. Clement on November 29, 2002. DEA has not received a request for hearing or any other reply from Dr. Clement or anyone purporting to represent him in this matter. Therefore, the Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Dr. Clement is deemed to have waived his hearing right. After considering material from the investigative file in this matter, the Deputy Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Dr. Clement currently possesses DEA Certificate of Registration AC3534814 and that registration remains valid until August 31, 2004. The Deputy Administrator further finds that by Opinion and Ruling dated July 31, 2002, the Louisiana State Board of Medical Examiners (Board) ordered the indefinite suspension of Dr. Clement's medical license. The suspension order arose out of Dr. Clement's refusal to undergo inpatient evaluation to ascertain whether he suffered from ''a psychiatric, neurologic (sic) or physical condition which render[ed] him incapable of practicing medicine with reasonable skill and safety to patients.''

The investigative file contains no evidence that the Board's suspension order has been stayed or that Dr. Clement's medical license has been reinstated. Therefore, the Deputy Administrator finds that Dr. Clement is not currently authorized to practice medicine in the State of Louisiana. As a result, it is reasonable to infer that he is also without authorization to handle controlled substances in that state.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in the state in which he conducts business. *See* 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. *See* Ramona K. Morris, M.D., 67 FR 68687 (2002); Dominick A. Ricci, M.D., 58 FR 51104 (1993); Bobby Watts, M.D., 53 FR 11919 (1988).

Here, it is clear that Dr. Clement's medical license has been indefinitely suspended, and as a result, he is not licensed to handle controlled substances in the State of Louisiana where he is registered with DEA. Therefore, he is not entitled to a DEA registration in that state.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AC3534814, issued to Richard J. Clement, M.D. be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective April 14, 2003.

Dated: February 27, 2003.

**John B. Brown III,**

*Deputy Administrator.*

[FR Doc. 03–6102 Filed 3–12–03; 8:45 am]

BILLING CODE 4410–09–M

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances Notice of Registration

By Notice dated July 9, 2002, and published in the **Federal Register** on August 6, 2002, (67 FR 50899), Penick Corporation, 158 Mount Olivet Avenue, Newark, New Jersey 07114, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

| Drug | Schedule |
|---|---|
| Codeine (9050) | II |
| Dihydrocodeine (9120) | II |
| Oxycodone (9143) | II |
| Hydromorphone (9150) | II |
| Hydrocodone (9193) | II |
| Morphine (9300) | II |
| Thebaine (9333) | II |
| Oxymorphone (9652) | II |

The firm plans to bulk manufacture the listed controlled substances for the manufacture of bulk pharmaceutical controlled substances.

No comments or objections have been received. DEA has considered the factors in Title 21, U.S. section 823(a) and determined that the registration of Penick Corporation to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Penick Corporation to ensure that the company's registration is consistent with the public interest. This investigation included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistance Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: February 28, 2003.

**Laura M. Nagel,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 03–6064 Filed 3–12–03; 8:45 am]

BILLING CODE 4410–09–M

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Manufacturer of Controlled Substances; Notice of Registration

By notice dated June 14, 2002, and published in the **Federal Register** on June 28, 2002, (67 FR 43684), Sigma Aldrich Research Biochemicals, Inc., Attn: Richard Milius, 1–3 Strathmore Road, Natick, Massachusetts 01760, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

| Drug | Schedule |
|---|---|
| Cathinone (1235) | I |
| Methcathinone (1237) | I |
| Aminorex (1585) | I |
| Alpha-Ethyltryptamine (7249) | I |
| Lysergic acid diethylamide (7315) | I |
| Tetrahydrocannabinols (7370) | I |
| 4-Bromo-2,5-dimethoxyamphetamine (7391). | I |
| 4-Bromo-2,5-dimethoxyamphetamine (7392). | I |
| 2,5-Dimethoxyamphetamine (7396). | I |
| 3,4-Methylenedioxyamphetamine (7400). | I |

| Drug | Schedule |
|---|---|
| N-Hydroxy-3,4-methlenedioxyamphetamine (7402). | I |
| 3,4-Methylenedioxy-N-ethylamphetamine (7404). | I |
| 3,4-Methylenedioxymethamphetamine (7405). | I |
| 1-[1-(2-Thienyl)cyclohexyl]piperidine (7470). | I |
| Heroin (9200) | I |
| Normorphine (9313) | I |
| Amphetamine (1100) | II |
| Methamphetamine (1105) | II |
| Nabilone (7379) | II |
| Phenylcyclohexylamine (7460) | II |
| Phencyclidine (7471) | II |
| Cocaine (9041) | II |
| Codeine (9050) | II |
| Diprenorphine (9058) | II |
| Benzoylecgonine (9180) | II |
| Levomethorphan (9210) | II |
| Levorphanol (9220) | II |
| Meperidine (9230) | II |
| Metazocine (9240) | II |
| Methadone (9250) | II |
| Morphine (9300) | II |
| Thebaine (9333) | II |
| Carfentanil (9743) | II |
| Levo-alphacetylmethadol (LAAM) (9648). | II |
| Fentanyl (9801) | II |

The firm plans to manufacture the listed controlled substances for laboratory reference standards and neurochemicals.

DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Sigma Aldrich Research Biochemicals, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Sigma Aldrich Research Biochemicals, Inc. on a regular basis to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: February 28, 2003.

**Laura M. Nagel,**

*Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.*

[FR Doc. 03–6065 Filed 3–12–03; 8:45 am]

BILLING CODE 4410–09–M

## DEPARTMENT OF JUSTICE

## Drug Enforcement Administration

## Douglas W. Wooldridge, M.D.; Revocation of Registration

On March 18, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Douglas W. Wooldridge, M.D. (Dr. Wooldridge) of Wellesley Hills, Massachusetts, notifying him of an opportunity to show cause as to why DEA should not revoke his DEA Certificate of Registration, AW1232088 under 21 U.S.C. 824(a), and deny any pending applications for renewal of that registration pursuant to 21 U.S.C. 823(f). As a basis for revocation, the Order to Show Cause alleged that Dr. Wooldridge is not currently authorized to practice medicine or handle controlled substances in the Commonwealth of Massachusetts, the state in which he practices. The order also notified Dr. Wooldridge that should no request for a hearing be filed within 30 days, his hearing right would be deemed waived.

The Order to Show Cause was sent by certified mail to Dr. Wooldridge at his registered location in Wellesley Hills, Massachusetts. On June 6, 2002, DEA received a signed receipt notification indicating that the Order to Show Cause was apparently forwarded from Dr. Wooldridge's registered location to a second location where it was received by a John Wooldridge on March 27, 2002. DEA has not received a request for hearing or any other reply from Dr. Wooldridge or anyone purporting to represent him in this matter. Therefore, the Deputy Administrator, finding that (1) 30 days have passed since the receipt of the Order to Show Cause, and (2) no request for a hearing having been received, concludes that Dr. Wooldridge is deemed to have waived his hearing right. After considering material from the investigative file in this matter, the Deputy Administrator now enters his final order without a hearing pursuant to 21 CFR 1301.43(d) and (e) and 1301.46.

The Deputy Administrator finds that Dr. Wooldridge currently possesses DEA Certificate of Registration AW1232088 and that registration remains valid until May 31, 2003. The Deputy Administration further finds that by Order dated June 13, 2001, the Massachusetts Board of Registration in Medicine (Board) ordered the suspension of Dr. Wooldridge's medical license. The suspension order arose out of Dr. Wooldridge's apparent failure to comply with terms of a probation agreement that he entered into with the Board on March 3, 1999.

The investigative file contains no evidence that the Board's suspension order has been stayed or that Dr. Wooldridge's medical license has been reinstated. Therefore, the Deputy Administrator finds that Dr. Wooldridge is not currently authorized to practice medicine in the Commonwealth of Massachusetts. As a result, it is reasonable to infer that he is also without authorization to handle controlled substances in Massachusetts.

DEA does not have statutory authority under the Controlled Substances Act to issue or maintain a registration if the applicant or registrant is without state authority to handle controlled substances in the state in which he conducts business. See 21 U.S.C. 802(21), 823(f) and 824(a)(3). This prerequisite has been consistently upheld. See Muttaiya Darmarajeh, M.D., 66 FR 52936 (2001); Dominick A. Ricci, M.D., 58 FR 51104 (1993); Bobby Watts, M.D., 53 FR 11919 (1988).

Here, it is clear that Dr. Wooldridge's medical license has been suspended, and as a result, he is not licensed to handle controlled substances in the Commonwealth of Massachusetts where he is registered with DEA. Therefore, he is not entitled to a DEA registration in that state.

Accordingly, the Deputy Administrator of the Drug Enforcement administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration AW1232088, issued to Douglas W. Wooldridge, M.D. be, and it hereby is, revoked. The Deputy Administrator further orders that any pending applications for renewal of such registration be, and they hereby are, denied. This order is effective April 14, 2003.

Dated: February 27, 2003.

**John B. Brown III,**

*Deputy Administrator.*

[FR Doc. 03–6101 Filed 3–12–03; 8:45 am]

BILLING CODE 4410–09–M

## DEPARTMENT OF LABOR

### Office of the Secretary

### Submission for OMB Review; Comment Request

March 6, 2003.

The Department of Labor (DOL) has submitted the following public information collection reqest (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation contact Darrin King at (202) 693–4129 or E-Mail *King-Darrin@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for EBSA, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate 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;
- 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;
- Enhance the quality, utility, and clarity of the information to be collected; and 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.

*Agency:* Employee Benefits Security Administration (EBSA).

*Type of Review:* Extension of a currently approved collection.

*Title:* Definition of Plans Assets—Participant Contributions.

*OMB Number:* 1210–0100.

*Affected Public:* Business or other for-profit and not-for-profit institutions.

*Frequency:* On occasion.

*Type of Response:* Recordkeeping, reporting, and third party disclosure.

*Number of Respondents:* 1.

*Number of Annual Responses:* 251.

*Estimated Time Per Respondent:* 3 hours.

*Total Burden Hours:* 3.

*Total Annualized Capital/Startup Costs:* $0.

*Total Annual Costs (operating/maintaining systems or purchasing services):* $332.

*Description:* Sponsors and other parties-in-interest to Employee Retirement Income Security Act (ERISA)—covered pension plans that cannot segregate employee contributions from the employer's general assets in the time required under ERISA are provided with an extension procedure. 29 CFR 2510.3–102 provides guidance for fiduciaries, participants, and beneficiaries of employee benefit plans on the requirements for transmission of employee contributions withheld from wages to the pension plan. In addition, for these employers who may have difficulty meeting regulation deadlines for participant contribution transmissions, the extension provision of the regulation provides an alternate means of employer compliance with the regulation while providing participants, beneficiaries, and the Department with sufficient information to protect their rights under ERISA. Specifically, the ICR includes notification, bonding, and certification requirements that must be completed by the employer electing to use the extension provision.

**Ira L. Mills,**

*Departmental Clearance Officer.*

[FR Doc. 03–6046 Filed 3–12–03; 8:45 am]

**BILLING CODE 4510–29–M**

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## DEPARTMENT OF LABOR

### Office of the Secretary

### Submission for OMB Review; Comment Request

March 3, 2003.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation contact Darrin King on (202) 693–4129 or E-Mail: *King.Darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ETA, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), within 30 days from the date of this publication in the **Federal Register.**

The OMB is particularly interested in comments which:

- Evaluate 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;
- 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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- 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.

*Agency:* Employment and Training Administration (ETA).

*Type of Review:* Extension of a currently approved collection.

*Title:* Distribution of Characteristics of the Insured Unemployed.

*OMB Number:* 1205–0009.

*Affected Public:* State, Local, or Tribal Government.

*Type of Response:* Reporting.

*Frequency:* Monthly.

*Number of Respondents:* 53.

*Annual Responses:* 636.

*Average Time Per Response:* 20 minutes.

*Total Annual Burden Hours:* 212.

*Total Annualized Capital/Startup Costs:* $0.

*Total Annual Costs (operating/maintaining systems or purchasing services):* $0.

*Description:* The ETA–203 report is the only source of current, consistent democraphic information on the Unemployed Insurance (UI) claim population. These characteristics identify important claimant cohorts for legislation, economic and social planning purposes, and the evaluation of the UI program on the Federal and State levels.

**Ira L. Mills,**

*Departmental Clearance Officer.*

[FR Doc. 03–6047 Filed 3–12–03; 8:45 am]

**BILLING CODE 4510–30–M**

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## MISSISSIPPI RIVER COMMISSION

### Sunshine Act Meetings

**AGENCY:** Mississippi River Commission.

**TIME AND DATE:** 9 a.m., April 7, 2003.

**PLACE:** On board MISSISSIPPI V at City Front, Cape Girardeau, MO.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:** (1) Summary report by President of the Commission on national and regional issues affecting the U.S. Army Corps of Engineers and Commission programs and projects on the Mississippi River and its tributaries; (2) District Commander's overview of current project issues within the Memphis District; and (3) Presentations by local organizations and members of the public giving views or comments on any issue affecting the programs or projects of the Commission and the Corps of Engineers.

**TIME AND DATE:** 9 a.m., April 8, 2003.

**PLACE:** On board MISSISSIPPI V at Mud Island, Memphis, TN.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:** (1) Summary report by President of the Commission on national and regional issues affecting the U.S. Army Corps of Engineers and Commission programs and projects on the Mississippi River and its tributaries; (2) District Commander's overview of current project issues within the Memphis District; and (3) Presentations by local organizations and members of the public giving views or comments on any issue affecting the programs or projects of the Commission and the Corps of Engineers.

**TIME AND DATE:** 9 a.m. April 9, 2003.

**PLACE:** On board MISSISSIPPI V at City Front, Greenville, MS

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:** Summary report by President of the Commission on national and regional issues affecting the U.S. Army Corps of Engineers and Commission programs and projects on the Mississippi River and its tributaries; (2) District Commander's overview of current project issues within the Vicksburg District and; (3) presentations by local organizations and members of the public giving views or comments on any issue affecting the programs or projects of the Commission and the Corps of Engineers.

**TIME AND DATE:** 9 a.m. April 11, 2003.

**PLACE:** On Board MISSISSIPPI V at New Orleans District Dock, Foot of Prytania Street, New Orleans, LA.

**STATUS:** Open to the Public.

**MATTERS TO BE CONSIDERED:** (1) Summary report by President of the Commission on national and regional issues affecting the U.S. Army Corps of Engineers and Commission programs and projects on the Mississippi River and its tributaries; (2) District Commander's overview of current project issues within the New Orleans District; and (3) Presentations by local organizations and members of the public giving view or comments on any issue affecting the programs or of the Commission and the Corps of Engineers.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Stephen Gambrell, telephone 601–634–5766.

**Luz D. Ortiz,**

*Army Federal Register Liaison Officer.*

[FR Doc. 03–6165 Filed 3–11–03; 11:43 am]

**BILLING CODE 3710–6X–M**

## NATIONAL SCIENCE FOUNDATION

### Notice of Intent to Seek Approval to Establish an Information Collection

**AGENCY:** National Science Foundation.

**ACTION:** Notice and request for comments.

**SUMMARY:** The National Science Foundation (NSF) is announcing plans to request clearance of this collection. In accordance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting that OMB approve clearance of this collection for no longer than three years.

**DATES:** Written comments on this notice must be received by May 12, 2003 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

**FOR FURTHER INFORMATION OR COMMENTS:** Contact Teresa R. Pierce, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230; telephone (703) 292–7555; or sent email to *tpierce@nsf.gov*. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. to 8 p.m., Eastern time, Monday through Friday. You also may obtain a copy of the data collection instrument and instructions from Ms. Pierce.

**SUPPLEMENTARY INFORMATION:**

*Title of Collection:* Survey of IGERT recipients.

*OMB Number:* 3145–NEW.

*Expiration Date of Approval:* Not applicable.

*Type of Request:* Intent to seek approval to establish an information collection.

**Abstract**

The Integrative Graduate Education and Research Traineeship (IGERT) program was initiated in 1997 and now comprises approximately 100 award sites. The IGERT program has been developed to meet the challenges of educating U.S. Ph.D. scientists, engineers, and educators with the interdisciplinary backgrounds, deep knowledge in chosen disciplines, and technical, professional, and personal skills to become in their own careers the leaders and creative agents for change. The program is intended to catalyze a cultural change in graduate education, for students, faculty, and institutions, by establishing innovative new models for graduate education and training in a fertile environment for collaborative research that transcends traditional disciplinary boundaries. It is also intended to facilitate greater diversity in student participation and preparation, and to contribute to the development of a diverse, globally-engaged science and engineering workforce. As part of this endeavor, IGERT awardees are expected to integrate instruction in ethics and the responsible conduct to research into their training programs. However, no mechanism is currently in place to determine (1) Whether such instruction occurs once the award is made, and (2) whether such instruction meets its goals. Thus, the NSF would like to survey IGERT recipients to answer the above questions.

**Proposed Project**

IGERT awardees will be invited, via email correspondence, to access a web-based survey document by a given date. This survey encompasses 22 questions, some with multiple parts, and is designed to assess the presence and relative strengths and weaknesses of any ethics training programs offered as part of the IGERT program at the awardee's institution.

*Use of the Information:* The results of the survey will be used to update Program Announcements and annual report requirements to reflect NSF's desire to promote the development of ethically trained scientists. Any additional reports developed with the survey results will be distributed to all IGERT awardees.

*Estimate of Burden:* 60 minutes per respondent, for 100 respondents, totaling 100 hours.

*Respondents:* Individuals.

*Estimated Number of Responses per Report:* 1.

*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 of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (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.

Dated: March 7, 2003.

**Suzanne H. Plimpton,**

*Reports Clearance Officer, National Science Foundation.*

[FR Doc. 03–5959 Filed 3–12–03; 8:45 am]

**BILLING CODE 7555–01–M**

## 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:

Regulation S–P; SEC File No. 270–480; OMB Control No. 3235–0537.

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 (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

• Regulation S–P—Privacy of Consumer Financial Information

On June 22, 2000, effective November 13, 2000, the Commission adopted Regulation S–P under the Securities Exchange Act of 1934 (''Exchange Act'') to implement title V of the Gramm-Leach-Bliley Act (''G–L–B Act'' or ''Act''). Among other things, title V of the G–L–B Act requires that at the time of establishing a customer relationship with a consumer and not less than annually during the continuation of such relationship, a financial institution shall provide a clear and conspicuous disclosure to such consumer of such financial institution's policies and practices with respect to disclosing nonpublic personal information to affiliates and nonaffiliated third parties (''privacy notice''). Title V of the Act also provides that, unless an exception applies, a financial institution may not disclose nonpublic personal information of a consumer to a nonaffiliated third party unless the financial institution clearly and conspicuously discloses to the consumer that such information may be disclosed to such third party; the consumer is given the opportunity, before the time that such information is initially disclosed, to direct that such information not be disclosed to such third party; and the consumer is given an explanation of how the consumer can exercise that nondisclosure option (''opt out notice'').

The privacy notices required by the Act are mandatory. The opt out notices are not mandatory for financial institutions that do not share nonpublic personal information with nonaffiliated third parties except as permitted under an exception to the statute's opt out provisions. Regulation S–P implements the statute's requirements with respect to broker-dealers, investment companies, and registered investment advisers (''covered entities''). The Act and Regulation S–P also contain consumer reporting requirements. In order for consumers to opt out, they must respond to opt out notices. At any time during their continued relationship, consumers have the right to change or update their opt out status. Most covered entities do not share nonpublic personal information with nonaffiliated third parties and therefore are not required to provide opt out notices to consumers under Regulation S–P. Therefore, few consumers are required to respond to opt out notices under the rule.

Compliance with Regulation S–P is necessary for covered entities to achieve compliance with the consumer financial privacy notice requirements of title V of the G–L–B Act. The required consumer notices are not submitted to the Commission. Because the notices do not involve a collection of information by the Commission, Regulation S–P does not involve the collection of confidential information. Regulation S–P does not have a record retention requirement per se, although the notices to consumers it requires are subject to the recordkeeping requirements of rules 17a–3 and 17a–4.

Currently, there are approximately 18,500 covered entities (approximately 5,600 broker-dealers that conduct business with the general public, 5,100 investment companies, and 7,800 registered investment advisers) that must prepare or revise the annual and initial privacy notices they provide to their customers. To prepare or revise their privacy notices, each of the approximately 10,700 covered entities that is a broker-dealer or investment company requires an estimated 40 hours at a cost of $5,248 (32 hours of professional time at $160 per hour plus 8 hours of clerical or administrative time at $16 per hour) and each of the approximately 7,800 covered entities that is a registered investment adviser requires an estimated 5 hours at a cost of $656 (4 hours of professional time at $160 per hour plus 1 hour of clerical or administrative time at $16 per hour). Thus, the total compliance burden per year is 740,000 hours (40 hours for 10,700 broker-dealers and investment companies, and 5 hours for 7,800 registered investment advisers ($40 \times 10{,}700 = 428{,}000$, $5 \times 7{,}800 = 39{,}000$, and $428{,}000 + 39{,}000 = 467{,}000$), and $57,401,600 ($\$5{,}248 \times 10{,}700 = \$56{,}153{,}600$, $\$160 \times 7{,}800 = \$1{,}248{,}000$, and $\$56{,}153{,}600 + \$1{,}248{,}000 = \$57{,}401{,}600$).

It is not anticipated that covered entities will need to incur any capital or start-up cost to comply with Regulation S–P. However, covered entities generally will include initial and annual privacy notices to customers with disclosure documents or account statements that they currently receive. These statements typically are assembled and sent by organizations that specialize in mailing and distribution. The additional material might result in an increase in total annual distribution costs of approximately $2.6 million for all covered entities. This estimate is based on an average additional cost per mailing of $0.02 for 130.7 million investor accounts. The number of investor accounts assumes there are 53 million brokerage accounts, 77.3 million individual investment company shareholders, and 400,000 customers of investment advisers.

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 shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the proposed collection of information; (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: March 6, 2003.

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–5992 Filed 3–12–03; 8:45 am]

BILLING CODE 8010–01–P

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47450; File No. SR–Amex–2003–02]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change and Amendment No. 1 Thereto by the American Stock Exchange LLC Relating to an Extension of the Interim Intermarket Linkage Program

March 5, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and rule 19b–4 thereunder,[2] notice is hereby given that on January 27, 2003, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission the proposed rule change as described in items I and II below, which items have been prepared by the Amex. The Exchange submitted Amendment No. 1 to the proposed rule change on March 4, 2003.[3] The Exchange filed the proposed rule change pursuant to section 19(b)(3)(A) of the Act,[4] and rule 19b–4(f)(6) thereunder,[5] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter to Jennifer Lewis, Division of Market Regulation, Commission, from Jeffrey P. Burns, Assistant General Counsel, Amex, dated March 4, 2003 (''Amendment No. 1''). In Amendment No. 1, Amex proposes that the extension of its interim linkage expire on January 31, 2003.

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6). The Amex requests that the Commission waive the 30-day operative delay. The Amex provided the Commission with notice of its intention to file this proposal on January 22, 2003.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to extend until January 31, 2003, the pilot program providing for the implementation of ''interim linkages'' with the other option exchanges.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Amex has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The purpose of this proposed rule change is to request an extension of the ''interim'' intermarket options linkage.[6] Currently, the Exchange is operating the interim linkage on a pilot basis pursuant to Amex rule 940. The interim linkage utilizes the Exchange's existing systems to facilitate the sending and receiving of order flow between Amex specialists and their counterparts on the other option exchanges as an interim step towards development of a permanent linkage in the options market.[7] The Exchange now proposes that the interim linkage remain in effect on a pilot basis until January 31, 2003.

For the reasons stated above, the Amex requests an extension of the pilot program until January 31, 2003.

[6] On January 31, 2002, the Commission extended the Exchange's Interim Linkage until December 31, 2002. *See* Securities Exchange Act Release No. 45373 (January 31, 2002), 67 FR 5860 (February 7, 2002) (File No. SR–Amex–2002–03). The Commission previously approved the Interim Linkage, on a pilot basis, for all options exchanges. *See* Securities Exchange Act Release Nos. 43904 (January 30, 2001), 66 FR 9112 (February 6, 2001) (File Nos. SR–ISE–00–15 and SR–CBOE–00–58); 43986 (February 20, 2001), 66 FR 12578 (February 27, 2001) (File No. SR–PCX–2001–10); 44271 (May 7, 2001), 66 FR 26887 (May 15, 2001) (File No. SR–Amex–2001–20); and 44311 (May 16, 2001), 66 FR 28768 (May 24, 2001) (File No. SR–Phlx–2001–52).

[7] The Commission approved the Plan for the Purpose of Creating and Operating an Intermarket Options Linkage in July 2000. *See* Securities Exchange Act Release No. 43086 (July 28, 2000), 65 FR 48023 (August 4, 2000).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with section 6(b) of the Act,[8] in general, and furthers the objectives of section 6(b)(5),[9] in particular, because it should prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system, and, in general, protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Amex does not believe that the proposed rule change will impose any burden on competition.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

No written comments were solicited or received with respect to the proposed rule change.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; (3) does not become operative for 30 days from the date of filing, or such shorter date as the Commission may designate, if consistent with the protection of investors and the public interest; and (4) the Exchange provided the Commission with notice of its intent to file the proposed rule change at least five days prior to the filing date, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act[10] and rule 19b–4(f)(6)[11] thereunder.

A proposed rule change filed under rule 19b–4(f)(6)[12] does not become operative prior to 30 days after the date of filing or such shorter time as the Commission may designate if such action is consistent with the protection of investors and the public interest. The Amex has requested, in order to permit the uninterrupted operation of the interim linkage, that the Commission accelerate the implementation of the proposed rule change so that it may take effect prior to the 30 days specified in

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6).

rule 19b–4(f)(6)(iii).[13] The Commission believes waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Acceleration of the operative date will permit operation of the interim options linkage to continue uninterrupted.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to File Number SR-Amex-2003–02 and should be submitted by April 3, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[15]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–5993 Filed 3–12–03; 8:45 am]

**BILLING CODE 8010–01–P**

[13] 17 CFR 240.19b–4(f)(6)(iii).

[14] For purposes of accelerating the implementation of the proposed rule change only, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47446; File No. SR–Amex–2002–105]**

## Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto by the American Stock Exchange LLC To Amend Amex Rule 17 to Provide for ''Cash'' In Addition to ''Next Day'' Settlement of Transactions in Rights and Warrants During the Trading Days Prior to Expiration

March 5, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and rule 19b–4 thereunder,[2] notice is hereby given that on December 12, 2002, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in items I, II and III below, which items have been prepared by the Exchange. The Amex filed an amendment to the proposed rule change on January 23, 2003.[3] The Commission is publishing this notice to solicit comments on the proposed rule change and Amendment No. 1 from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to amend Amex rule 17 to provide for ''cash'' in addition to ''next day'' settlement of transactions in rights and warrants during the trading days prior to expiration. The text of the proposed rule change is below. Text in brackets indicates material to be deleted, and text in italics indicates material to be added.

* * * * *

**Transactions in Rights and Warrants**

Rule 17. (a) Unless otherwise directed by the Exchange, dealings on the Exchange in an issue of rights or warrants shall cease in accordance with the following procedure:

(1) Dealings in an issue of rights shall cease at the close of business on the business day preceding the expiration date thereof, if such rights are exercisable in the New York City metropolitan area, and at such time in advance of the expiration date as may be announced by the Exchange, if such rights are exercisable outside such area; and

(2) Dealings in an issue of warrants shall cease, in the case of book-entry warrants, at the close of business on their expiration date, and for all other warrants at the close of business on the last business date preceding their expiration date.

(b) During the three business days preceding the final day for dealings therein on the Exchange, all transactions in an issue of rights shall be made only ''next day[.]'' *or for ''cash''.* On the final day for dealings therein on the Exchange, all transactions in an issue of rights shall be made only for ''cash.''

(c) During the three final business days for trading in an issue of warrants, dealings on the Exchange shall be made only for ''cash.'' During the three preceding business days dealings on the Exchange shall be made only ''next day[.]'' *or for ''cash'.*

* * * Commentary

See rule 179 for treatment of orders on a specialist's book during the final days for dealings in rights or warrants.

* * * * *

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change, as amended, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

Amex rule 17(b) currently provides that transactions in rights during the three trading days preceding the last trading session must be settled on a ''next day'' basis. Amex rule 17(c) currently provides that transactions in warrants during the three trading days preceding the last three trading sessions (*i.e.*, the fourth, fifth and sixth trading sessions prior to expiration) must only

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from William Floyd-Jones, Jr., Assistant General Counsel, Amex, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, dated January 21, 2003, replacing Form 19b–4 in its entirety (''Amendment No. 1''). In Amendment No. 1, the Amex made corrections to rule text in Amex rule 17(b) to allow for ''cash'' settlement as well as ''next day'' settlement for all transactions in an issue of rights during the three business days preceding the final day for dealings on the Exchange and made corresponding changes and corrections to its discussion in the rule filing.

be effected on a ''next day'' basis. The Exchange believes that there is no reason why trades should not be settled for ''cash'' at any time during the final six days prior to expiration, and is proposing to amend Amex rule 17 to allow ''cash'' settlement during all of the final six days of trading in any right or warrant on the Exchange.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, is consistent with section 6(b) of the Act [4] in general, and furthers the objectives of section 6(b)(5) of the Act [5] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that the proposed rule change, as amended, will impose no burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

No written comments were solicited or received in response to the proposed rule change.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change, as amended, that are filed with the Commission, and all written communications relating to the proposed rule change, as amended, between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Amex. All submissions should refer to file number SR-Amex-2002–105 and should be submitted by April 3, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–5994 Filed 3–12–03; 8:45 am]

BILLING CODE 8010–01–P

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47455; File No. SR–Amex–2003–15]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange LLC To Extend the Suspension of Transaction Charges for Certain Exchange-Traded Funds

March 6, 2003.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 4, 2003, the American Stock Exchange LLC (''Amex'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Amex proposes to extend until March 31, 2003 the suspension of Exchange transaction charges for specialist, Registered Trader and broker-dealer orders for the iShares Lehman 1–3 year Treasury Bond Fund; iShares Lehman 7–10 year Treasury Bond Fund; Treasury 10 FITR ETF; Treasury 5 FITR ETF; Treasury 2 FITR ETF; and Treasury 1 FITR ETF. In addition, the Exchange proposes to suspend until March 31, 2003 customer transaction charges for the iShares S&P 100 Index Fund. Proposed new language is *italicized*; proposed deletions are in [brackets].

* * * * *

AMEX EQUITY FEE SCHEDULE

1. Transaction Charges
   No change.

II. Regulatory Fee
   No Change.
   Notes:
   1. and 2. No change.
   3. Customer transaction charges for the following Portfolio Depositary Receipts, Index Fund Shares, and Trust Issued Receipts have been suspended:

DIA—DIAMONDS®
QQQ—Nasdaq–100® Index Tracking Stock
SPY–SPDRs®
IVV—iShares S&P 500
MDY—MidCap SPDRs
XLY—Select Sector SPDR—Consumer Discretionary
XLP—Select Sector SPDR—Consumer Staples
XLE—Select Sector SPDR—Energy
XLF—Select Sector SPDR—Financial
XLV—Select Sector SPDR—Health Care
XLI—Select Sector SPDR—Industrial
XLB—Select Sector SPDR—Materials
XLK—Select Sector SPDR—Technology
XLU—Select Sector SPDR—Utilities
BHH–B2B Internet HOLDRs™
BBH—Biotech HOLDRs
BDH—Broadband HOLDRs
EKH—Europe 2001 HOLDRs
IAH—Internet Architecture HOLDRs
HHH—Internet HOLDRs
IIH—Internet Infrasturcture HOLDRs
MKH—Market 2000+ HOLDRs
OIH—Oil Service HOLDRs
PPH—Pharmaceutical HOLDRs
RKH—Regional Bank HOLDRs
RTH—Retail HOLDRs
SMH—Semiconductor HOLDRs
SWH—Software HOLDRs
TTH—Telecom HOLDRs
UTH—Utilities HOLDRs
WMH—Wireless HOLDRs
SHY—iShares Lehman 1–3 Year Treasury Bond Fund
IEF—iShares Lehman 7–10 Year Treasury Bond Fund

TLT—iShares Lehman 20+ Year Treasury Bond Fund
LQD—iShares GS $ InvesTop Corporate Bond Fund
TFT—Treasury 1 FITR ETF
TOU—Treasury 2 FITR ETF
TFI—Treasury 5 FITR ETF
TTE—Treasury 10 FITR ETF

*Until March 31, 2003, customer transaction charges for the iShares S&p 100 Index Fund (OEF) have been suspended.*

Until [February 28] *March 31,* 2003, transaction charges also have been suspended in SHY, IEF, TFT, TOU, TFI and TTE for specialist, Registered Trader and broker dealer orders.

* * * * *

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Section A, B, and C below, of the most significant aspects of such statements.

### *A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange is extending until March 31, 2003 the suspension of transaction charges in iShares Lehman 1–3 year Treasury Bond Fund (Symbol: SHY); iShares Lehman 7–10 year Treasury Bond Fund (Symbol: IZEF); Treasury 10 FITR ETF (Symbol: TTE); Treasury 5 FITR ETF (TFI); Treasury 2 FITR ETF (TOU); and Treasury 1 FITR ETF (TFT) for specialist, Registered Trader and broker-dealer orders. The Exchange previously filed a suspension in such charges until November 30, 2002,[3] December 13, 2002,[4] January 31, 2003,[5] and February 28, 2003.[6] 2003.

The Exchange is also suspending customer transaction charges until March 31, 2003 for the iShares S&P 100 Index Fund (Symbol: OEF), an Exchange-Traded Fund that the Exchange will trade pursuant to unlisted trading privileges.

The Exchange believes a suspension of fees for these securities is appropriate to enhance the competitiveness of executions in these securities on the Amex. The Exchange will reassess the fee suspension as appropriate, and will file any modification to the fee suspension with the Commission pursuant to Section 19(b)(3)(A) of the 1934 Act.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[7] in general, and furthers the objectives of Section 6(b)(4)[8] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

The Exchange has neither solicited nor received comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6)[10] thereunder because the proposal: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative prior to 30 days after the date of filing such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange gave the Commission notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Act.

The Amex has requested that the Commission waive the 30-day operative delay. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission notes that fee suspensions for the exchange-trade funds that are the subject of this filing have been previously filed with the Commission.[11] Further, extension of the fee suspension for specialist, Registered Trader, and broker-dealer orders will permit the fee suspensions to continue uninterrupted. With regard to the iShares S&P 100 Index Fund, acceleration of the operative date will permit the Amex to suspend these fees immediately. For these reasons, the Commission designates the proposal to be effective and operative upon filing with the Commission.[12]

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Amex–2003–15 and should be submitted by April 3, 2003.

[3] *See* Securities Exchange Act Release No. 46765 (November 1, 2002), 67 FR 68893 (November 13, 2002) (SR–Amex–2002–91).

[4] *See* Securities Exchange Act Release No. 46996 (December 13, 2002), 67 FR 78264 (December 23, 2002) (SR–Amex–2002–98).

[5] *See* Securities Exchange Act Release No., 47141 (January 8, 2003), 68 FR 2090 (January 15, 2003) (SR–Amex–2002–115).

[6] *See* Securities Exchange Act Release No. 47361 (February 13, 2003), 68 FR 8534 (February 21, 2003 (SR–Amex–2003–04).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] *See supra* notes 3, 4, 5, and 6.

[12] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6068 Filed 3–12–03; 8:45 am]

BILLING CODE 8010–01–M

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47443; File No. SR–CHX–2002–40]**

## Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Stock Exchange, Inc. Relating to Zero-Second Display of Certain Limit Orders

March 4, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 26, 2002, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On January 10, 2003, the exchange filed an amendment to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.[4]

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Article XX, Regular Trading Sessions, CHX Rule 7, Recognized Quotations, and CHX Rule 37, Guaranteed Execution System and Midwest Automated Execution System, which govern, among other things, display of limit orders in a specialist's book. The text of the proposed rule change is below. Proposed new language is in italics.

**Chicago Stock Exchange Rules**

Article XX Regular Trading Sessions

* * * * *

**Recognized Quotations**

**RULE 7**

No change to text.

• • • **Interpretations and Policies:**

.01–.04 No change to text.

.05 (a) Quotation sizes, unless otherwise specified, shall be assumed to be for 100 shares. With respect to agency limit orders received by specialists, each specialist shall publish immediately (*i.e.,* as soon as practicable, which under normal circumstances means no later than 30 seconds from time of receipt, *subject to the provisions below relating to agency limit orders designated ''post protection only''*) a bid or offer that reflects:

(i) The price and full size of each agency limit order that is at a price that would improve the specialist's bid or offer in such security; and

(ii) The full size of each agency limit order that is priced equal to the specialist's bid or offer for such security.

(b) The requirements with respect to specialists' display of limit orders shall not apply to any limit order that is:

(i) Executed upon receipt of the order;

(ii) Placed by a person or entity who expressly requests, either at the time the order is placed or prior thereto pursuant to an individually negotiated agreement with respect to such person's orders, that the order not be displayed;

(iii) An odd-lot order;

(iv) Delivered immediately upon receipt to an exchange or association-sponsored system or an electronic communications network that complies with the requirements of Securities and Exchange Commission Rule 11Ac1–1(c)(5) under the Securities Exchange Act with respect to that order;

(v) Delivered immediately upon receipt to another exchange member or over-the-counter market maker that complies with the requirements of Securities and Exchange Commission Rule 11Ac1–4 under the Securities Exchange Act with respect to that order;

(vi) An all or none order; or

(vii) A block size order, unless the customer order is received with a request that the order be displayed.

*If a floor broker designates an agency limit order, in a manner specified by the Exchange, as ''post protection only,'' and sends that order to the specialist via the MAX system, the specialist receiving such order shall display the limit order in zero seconds. Such order will not be entitled to primary market price protection or other protections due limit orders under Article XX, Rule 37(a)(3).*

* * * * *

Guaranteed Execution System and Midwest Automated Execution System

* * * * *

RULE 37(a). Guaranteed Executions.

* * * * *

3. Dual Trading System Agency Limit Orders. Subject to Interpretation and Policy .10 (''Exempted Trade-Throughs''), all agency limit orders in Dual Trading System issues will be filled under the following circumstances:

(a) Exhaustion of primary market bid or offer. When the bid or offering at the limit price has been exhausted in the primary market (as defined in the CTA plan), agency limit orders will be executed in whole or in part, based on the rules of priority and precedence, on a share for share basis with trades executed at the limit price in the primary market;

(b) Price penetration in primary market. When there has been a price penetration of the limit in the primary market, agency limit orders that have resided in the specialist's book for a period of 0–15 seconds (as designated by the specialist) prior to the primary market print will be filled at the limit price;

(c) Primary market trading at the limit price. When the issue is trading at the limit price on the primary market, agency limit orders will be filled at the limit price unless it can be demonstrated that such orders would not have been executed if they had been transmitted to the primary market or the broker and specialist agree to a specific volume related or other criteria for requiring a fill; and

(d) Block size trade-through in another market. In instances where a block trade on the Exchange or other market against which orders are being protected takes place outside the current Exchange quotation, all effective bids or offers limited to the block price or better will be executed at the more favorable block price rather than at the limit price of the affected orders. A specialist may elect to provide automatic execution of designated limit orders at the block price or better when a ''block size'' (as defined in Article XX, Rule 40, Interpretation and Policy .05) trade-through is executed on the primary market.

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter, dated January 9, 2003, from Kathleen M. Boege, Associate General Counsel, CHX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission (''Amendment No. 1''). In Amendment No. 1, the CHX provided additional clarity as to the full extent of limit order protection that would be forfeited by a floor broker that elects ''post protection only'' (''PPO'') under the proposed rule change.

[4] The CHX requested that the Commission make various non-substantive typographical corrections to the notice in the rule language and purpose section. In addition, the CHX requested that the Commission add an additional protection related to block trades as described in footnote 7 below. Such protection was added due to an intervening CHX rule change that was not in place at the time of filing of the instant proposed rule change. Telephone conference between Kathleen M. Boege, Associate General Counsel, CHX, and Christopher B. Stone, Special Counsel, Division, Commission (March 3, 2003).

A specialist may elect automatic execution of such agency limit orders on an issue-by-issue basis. *The foregoing provisions of this Article XX, Rule 37(a)(3) shall not apply to limit orders designated by a floor broker as ''post protection only'' in accordance with the provisions of Article XX, Rule 7, Interpretation and Policy .05.*

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

### *A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to amend Article XX, Rules 7 and 37 of the CHX Rules, which govern, among other things, display of limit orders in a specialist's book and execution prices due certain limit orders. The proposed change would permit a CHX member (including a floor broker) to elect zero-second display by a CHX specialist of limit orders designated by the member as PPO orders.

Under Exchange Act Rule 11Ac1–4 [5] and current Article XX, Rule 7 (Interpretation and Policy .05) of the CHX Rules, a CHX specialist must display customer limit orders ''immediately,'' which means ''* * * as soon as practicable, which under normal market conditions means no later than 30 seconds from time of receipt.'' Although past studies have shown that CHX specialists, through the use of automated tools, display the vast majority of customer limit orders within zero seconds after they are required to do so, CHX specialists may choose to actually see one or more orders before deciding whether or not to execute the order, transfer the order to another marketplace or display the order at the Exchange.[6]

In some cases, however, customers expressly desire the zero-second display of their orders. Specifically, the CHX has been advised that, for certain customers of CHX floor brokers, zero-second display of their limit orders is often their paramount consideration. While CHX specialists may choose not to display each limit order in zero seconds—because they may wish to have the opportunity to decide whether or not to interact with certain limit orders—the CHX floor broker community has suggested a solution which protects the interests of CHX member order-sending firms and their customers, while permitting CHX specialists to appropriately handle limit orders.

Under the proposed rule change, PPO orders (as designated by a CHX floor broker) would be automatically displayed by the specialist in zero seconds without any opportunity for a specialist to interact with the order prior to display. PPO orders would be treated in accordance with applicable CHX rules governing priority and precedence, but would not be entitled to trade through protection by the CHX specialist in the event of a price penetration in the primary market.[7] This solution will afford CHX floor brokers the flexibility to elect zero-second display of their customers' limit orders in instances that render such immediacy of paramount concern. The proposal in turn does not require a specialist to provide subject limit orders with trade through protection or the other protections set forth in Article XX, Rule 37(a)(3), when the specialist has been denied the opportunity to interact with the order.

The CHX believes that the proposal is consistent with the interests of the investing public, as a floor broker will be able to elect zero-second display of a limit order when that display is either requested by the customer or otherwise is in a customer's interest.[8] In other instances, an order-sending firm may consider the protections of Article XX, Rule 37(a)(3) to constitute a better means of achieving its customer's goals, in which case the floor broker could elect to forego zero-second display.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of section 6(b) of the Act,[9] in general, and Section 6(b)(5) of the Act,[10] in particular, which requires, among other things, that the rules of an exchange be designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

The Exchange has neither solicited nor received written comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal**

[5] 17 CFR 240.11Ac1–4 (''Display Rule'').

[6] Specialists can help ensure that they meet their Display Rule obligations with respect to these manually handled orders by using additional automated functions, such as the default timers provided in the CHX trading system. These default timers, which can be set, among other things, from zero to 25 seconds (in listed securities) or from zero to 30 seconds (in over-the-counter (''OTC'') securities), ensure that eligible orders are automatically displayed when they improve a specialist's quote and when the timer setting has elapsed without the orders having been manually displayed, executed or transferred to another marketplace. In addition, the CHX Market Regulation Department actively surveils to ensure that CHX specialists do not routinely rely on their timers to extend the display period beyond what is necessary for the specialist to interact with the limit orders they receive.

[7] Under Article XX, Rule 37(a)(3), a limit order for a Dual Trading System (*i.e.*, listed) issue, which is resident in a CHX specialist's book for 15 seconds or more, generally is entitled to ''trade through protection,'' *i.e.*, execution at the limit price in the event of a price penetration in the primary market. Article XX, Rule 37(a)(3) also requires execution at the limit price, subject to certain conditions, (a) if the bid or offer has been exhausted in the primary market, (b) if the issue is trading at the limit price in the primary market, and (c) if a block trade has been printed on the Exchange or an away market at superior price. A floor broker electing PPO would also forego these protections otherwise due under Article XX, Rule 37(a)(3).

[8] Orders routed to a CHX floor broker constitute orders from sophisticated investors who choose to utilize the services of a floor broker because, among other reasons, the investor can communicate certain conditions regarding execution of the order, which conditions the floor broker will take into account in seeking liquidity to fill the order. Such investors possess sufficient market experience to fully evaluate the consequences of having their floor broker elect the PPO order option on their behalf. By restricting the PPO order option to floor brokers, the CHX believes that it will avoid instances where less sophisticated investors would elect zero-second display of their limit orders, without fully considering the ramifications of foregoing primary market protection of such limit orders.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

**Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, as amended, or

(B) institute proceedings to determine whether the proposed rule change, as amended, should be disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change, as amended, that are filed with the Commission, and all written communications relating to the proposed rule change, as amended, between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–CHX–2002–40 and should be submitted by April 3, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–5995 Filed 3–12–03; 8:45 am]

BILLING CODE 8010–01–P

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47449; File No. SR–ISE–2003–08]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the International Securities Exchange, Inc., Relating to Fee Changes

March 5, 2003.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 26, 2003, the International Securities Exchange, Inc. (''Exchange'' or ''ISE'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which items have been prepared by the ISE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange is proposing changes to its Schedule of Fees regarding complex orders. First, the Exchange proposes to charge its regular execution fees only on one leg of the complex order (as opposed to charging on each leg). Second, the Exchange proposes to waive all such execution fees for complex orders through June 30, 2003. Below is the text of the proposed rule change. Proposed new language is in *italics.*

* * * * *

ISE SCHEDULE OF FEES

[Electronic Market Place]

| Execution fees | Amount ($) | Billable unit | Frequency | Notes |
|---|---|---|---|---|
| Customer | 0.05 | contract/side | Transaction | Fee waived through June 30, 2003. |
| Facilitation | 0.15 | contract/side | Transaction | |
| Market Maker & Firm Proprietary (including members of other exchanges executing Linkage transactions, except Satisfaction Orders). | | | | *For Complex Orders, charged only for the leg of the trade consisting of the most contracts;* Firm Proprietary fees for trades executed in the Block Order Mechanism and for all trades in the iShares S&P 100 Index Fund waived through May 31, 2003; *fees for Complex Orders waived through June 30, 2003.* |
| A.D.V. Less Than 300,000 | 0.21 | contract/side | Transaction | Based on Exchange A.D.V. |
| A.D.V. From 300,001 to 500,000 | 0.17 | contract/side | Transaction | Based on Exchange A.D.V. |
| A.D.V. From 500,001 to 700,000 | 0.14 | contract/side | Transaction | Based on Exchange A.D.V. |
| A.D.V. Over 700,000 | 0.12 | contract/side | Transaction | Based on Exchange A.D.V. |

* * * * *

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange is proposing changes to its Schedule of Fees regarding complex orders in an attempt to provide its members with an incentive to execute complex orders on the Exchange.

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The Exchange currently applies its regular execution fees to complex orders. Because these trades generally are effected on low margins, the imposition of the regular execution fees may render some trades uneconomical. Accordingly, the Exchange proposes to charge its regular execution fees only on one leg of the complex order (as opposed to charging on each leg). Specifically, the Exchange would charge a fee on the leg with the most contracts.

For example, if there is a simple two-legged spread to buy 100 contracts of one series and to sell 100 contracts of another series, ISE would charge a fee for 100 contracts. In a three-legged trade of 100 contracts, 50 contracts and 50 contracts, ISE also would charge a fee for 100 contracts. In a complex trade with both an option and a non-option leg, ISE would charge a fee for the option leg.

In addition, the Exchange is proposing to waive all execution fees for complex orders through June 30, 2003.

2. Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(4) of the Act that an exchange have an equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities.[3]

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others*

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change, which establishes or changes a due, fee or other charge imposed by the Exchange, has become effective pursuant to Section 19(b)(3)(A) of the Act[4] and Rule 19b–4(f)(2)[5] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section. Copies of such filing will also be available for inspection and copying at the principal office of the ISE. All submissions should refer to File No. SR–ISE–2003–08 and should be submitted by April 3, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6067 Filed 3–12–03; 8:45 am]

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[3] 15 U.S.C. 78f(b)(4).

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 19b–4(f)(2).

[6] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47464; File No. SR–NASD–2003–22]**

## Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to the Listing and Trading of Market Recovery Notes Linked to the S&P 500 Index

March 7, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 26, 2003, the National Association of Securities Dealers, Inc. (''NASD'' or ''Association''), through its subsidiary, The Nasdaq Stock Market, Inc. (''Nasdaq''), filed with the Securities and Exchange Commission (''Commission'' or ''SEC'') the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and is approving the proposal on an accelerated basis.

**I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change**

Nasdaq proposes to list and trade Market Recovery Notes℠ Linked to the S&P 500® Index (''Notes'') issued by Merrill Lynch & Co., Inc. (''Merrill Lynch'').

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

Nasdaq proposes to list and trade notes, the return on which is based upon the S&P 500 Index (''Index'').[3]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Index is published by Standard & Poor's, a division of The McGraw-Hill Companies, Inc. (''Standard & Poor's'' or S&P'') and is intended to provide an indication of the pattern of common stock price movement. The Index is a capitalization-weighted index, with each stock's weight in the Index proportionate to its market value. The value of the Index is based on the relative value of the aggregate market value of the common stocks of 500 companies as of a particular time compared to the aggregate average market value of the common stocks of 500 similar companies during the base period of the years 1941 through 1943. The market value for the common stock of a company is the product of the market price per share of the common stock and the number of outstanding shares of common stock. As of January 31, 2003, 424 companies, or 85.5% of the market capitalization of the Index, traded on the New York Stock Exchange (''NYSE''); 74 companies, or 14.3% of the market capitalization of the Index traded on The Nasdaq Stock Market; and

Under NASD Rule 4420(f), Nasdaq may approve for listing and trading innovative securities that cannot be readily categorized under traditional listing guidelines.[4] Nasdaq proposes to list for trading the, as described below, under NASD Rule 4420(f).

Description of the Notes

The Notes are a series of senior non-convertible debt securities that will be issued by Merrill Lynch and will not be secured by collateral. The Notes will have a term of not less than one and not more than four years. The Notes will be issued in denominations of whole units (''Unit''), with each Unit representing a single Note. The original public offering price will be $10 per Unit. The Notes will not pay interest and are not subject to redemption by Merrill Lynch or at the option of any beneficial owner before maturity in 2004.[5]

At maturity, if the value of the S&P 500 Index has increased, a beneficial owner will be entitled to receive a payment on the Notes based on triple the amount of that percentage increase, not to exceed a maximum payment per Unit (the ''Capped Value'') that is expected to be between $11.60 and $12.00.[6] Thus, the Notes provide investors the opportunity to obtain leveraged returns based on the S&P 500 Index subject to a cap that is expected to represent an appreciation of 16% to 20% over the original public offering price of the Notes. Unlike ordinary debt securities, the Notes do not guarantee any return of principal at maturity. Therefore, if the value of the S&P 500 Index has declined at maturity, a beneficial owner will receive less, and possibly significantly less, than the original public offering price of $10 per Unit.[7]

The payment that a beneficial owner will be entitled to receive (the ''Redemption Amount'') depends entirely on the relation of the average of the values of the S&P 500 Index at the close of the market on five business days shortly before the maturity of the Notes (the ''Ending Value'') and the closing value of the S&P 500 Index on the date the Notes are priced for initial sale to the public (the ''Starting Value'').

If the Ending Value is less than or equal to the Starting Value, the Redemption Amount per Unit will equal:

$$\$10 \times \left( \frac{\text{Ending Value}}{\text{Starting Value}} \right)$$

If the Ending Value is greater than the Starting Value, the Redemption Amount per Unit will equal:

$$\$10 + \left( \$30 \times \left( \frac{\text{Ending Value} - \text{Starting Value}}{\text{Starting Value}} \right) \right)$$

provided, however, the Redemption Amount cannot exceed the Capped Value.

The Notes are cash-settled in U.S. dollars and do not give the holder any right to receive a portfolio security, dividend payments or any other ownership right or interest in the portfolio or index of securities comprising the S&P 500 Index. The Notes are designed for investors who want to participate or gain exposure to the S&P 500 Index, subject to a cap, and who are willing to forego market interest payments on the Notes during such term. The Commission has previously approved the listing of options on, and securities the performance of which have been linked to or based on, the S&P 500 Index.[8]

Criteria for Initial and Continued Listing

The Notes, which will be registered under section 12 of the Act, will initially be subject to Nasdaq's listing criteria for other securities under NASD Rule 4420(f). Specifically, under NASD Rule 4420(f)(1):

(A) The issuer shall have assets in excess of $100 million and stockholders' equity of at least $10 million. In the case of an issuer which is unable to satisfy the income criteria set forth in paragraph (a)(1), Nasdaq generally will require the issuer to have the following: (i) assets in excess of $200 million and stockholders' equity of at least $10 million; or (ii) assets in excess of $100 million and stockholders' equity of at least $20 million;

(B) There must be a minimum of 400 holders of the security, provided, however, that if the instrument is traded in $1,000 denominations, there must be a minimum of 100 holders;

(C) For equity securities designated pursuant to this paragraph, there must be a minimum public distribution of 1,000,000 trading units;

(D) The aggregate market value/principal amount of the security will be at least $4 million.

In addition, Nasdaq notes that Merrill Lynch satisfies the listed marketplace requirement set forth in NASD Rule

2 companies, or 0.2% of the market capitalization of the Index, traded on the American Stock Exchange (''AMEX''). As of January 31, 2003, the aggregate market value of the 500 companies included in the Index represented approximately 79% of the aggregate market value of stocks included in the Standard & Poor's Stock Guidance Database of domestic common stocks traded in the U.S., excluding American depositary receipts, limited partnerships and mutual funds. Standard & Poor's chooses companies for inclusion in the Index with the aim of achieving a distribution by broad industry groupings that approximates the distribution of these groupings in the common stock population of the Standard & Poor's Stock Guide Database, which Standard & Poor's uses as an assumed model for the composition of the total market. Relevant criteria employed by Standard & Poor's include the viability of the particular company, the extent to which that company represents the industry group to which it is assigned, the extent to which the market price of that company's common stock is generally responsive to changes in the affairs of the respective industry and the market value and trading activity of the common stock of that company. Ten main groups of companies comprise the Index with the percentage weight of the companies included in each group indicated in parentheses as of February 18, 2003: Consumer Discretionary (13.4%), Consumer Staples (9.4%), Energy (6.0%), Financials (20.6%), Health Care (15.3%), Industrials (11.3%), Information Technology (14.4%), Materials (2.8%), Telecommunication Services (4.0%), and Utilities (2.8%).

[4] *See* Securities Exchange Act Release No. 32988 (September 29, 1993); 58 FR 52124 (October 6, 1993) (order approving File No. SR–NASD–93–15), (''1993 Order'').

[5] The actual maturity date will be determined on the day the Notes are priced for initial sale to the public.

[6] The actual Capped Value will be determined at the time of issuance of the Notes.

[7] Any amount the beneficial owner would receive at maturity (which is less than the original offering price) would correspond to any decline in value of the S&P 500. Telephone conversation between John D. Nachmann, Senior Attorney, Nasdaq, and Florence E. Harmon, Senior Special Counsel, Division of Market Regulation (''Division''), Commission, on March 7, 2003.

[8] *See* Securities Exchange Act Release No. 19907 (June 24, 1983), 48 FR 30814 (July 5, 1983) (approving the listing and trading of options on the S&P 500 Index); Securities Exchange Act Release No. 31591 (December 11, 1992), 57 FR 60253 (December 18, 1992) (approving the listing and trading of Portfolio Depositary Receipts based on the S&P 500 Index); Securities Exchange Act Release No. 27382 (October 26, 1989), 54 FR 45834 (October 31, 1989) (approving the listing and trading of Exchange Stock Portfolios based on the value of the S&P 500 Index); and Securities Exchange Act Release No. 30394 (February 21, 1992), 57 FR 7409 (March 2, 1992) (approving the listing and trading of a unit investment trust linked to the S&P 500 Index).

4420(f)(2).[9] Lastly, pursuant to NASD Rule 4420(f)(3), prior to the commencement of trading of the Notes, Nasdaq will distribute a circular to members providing guidance regarding member firm compliance responsibilities and requirements, including suitability recommendations, and highlighting the special risks and characteristics of the Notes. In particular, Nasdaq will advise members recommending a transaction in the Notes to: (1) Determine that such transaction is suitable for the customer; and (2) have a reasonable basis for believing that the customer can evaluate the special characteristics of, and is able to bear the financial risks of, such transaction.

The Notes will be subject to Nasdaq's continued listing criterion for other securities pursuant to NASD Rule 4450(c). Under this criterion, the aggregate market value or principal amount of publicly-held units must be at least $1 million. The Notes also must have at least two registered and active market makers as required by NASD Rule 4450(a)(6). Nasdaq will also consider prohibiting the continued listing of the Notes if Merrill Lynch is not able to meet its obligations on the Notes.

Rules Applicable to the Trading of the Notes

Since the Notes will be deemed equity securities for the purpose of NASD Rule 4420(f), the NASD and Nasdaq's existing equity trading rules will apply to the Notes. First, pursuant to NASD Rule 2310, ''Recommendations to Customers (Suitability),'' and NASD IM–2310–2, ''Fair Dealing with Customers,'' NASD members must have reasonable grounds for believing that a recommendation to a customer regarding the purchase, sale or exchange of any security is suitable for such customer upon the basis of the facts, if any, disclosed by such customer as to his other security holdings and as to his financial situation and needs.[10] In addition, as previously described, Nasdaq will distribute a circular to members providing guidance regarding compliance responsibilities and requirements, including suitability recommendations, and highlighting the special risks and characteristics of the Notes. Furthermore, the Notes will be subject to the equity margin rules. Lastly, the regular equity trading hours of 9:30 a.m. to 4 p.m. will apply to transactions in the Notes.

Nasdaq represents that NASD's surveillance procedures are adequate to properly monitor the trading of the Notes. Specifically, NASD will rely on its current surveillance procedures governing equity securities, and will include additional monitoring on key pricing dates. In addition, Nasdaq has a general policy that prohibits the distribution of material, non-public information by it employees.

Disclosure and Dissemination of Information

Merrill Lynch will deliver a prospectus in connection with the initial purchase of the Notes. The procedure for the delivery of a prospectus will be the same as Merrill Lynch's current procedure involving primary offerings. In addition, Nasdaq will issue a circular to NASD members explaining the unique characteristics and risks of the Notes.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of section 15A of the Act,[11] in general, and with section 15A(b)(6) of the Act,[12] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments were neither solicited nor received.

**III. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–2003–22 and should be submitted by April 3, 2003.

**IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change**

Nasdaq has asked the Commission to approve the proposal, on an accelerated basis to accommodate the timetable for listing the Notes. The Commission notes that it has previously approved the listing of options on, and securities the performance of which have been linked to or based on, the S&P 500 Index.[13] The Commission has also previously approved the listing of securities with a structure identical to that of the Notes.[14]

After care consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder, applicable to a national securities association, and, in particular, with the requirements of

[9] NASD Rule 4420(f)(2) generally requires that issuers of securities designated pursuant to this paragraph [sic] to be listed on The Nasdaq National Market or the NYSE or be an affiliate of a company listed on The Nasdaq National Market or the NYSE; provided, however, that the provisions of NASD Rule 4450 will be applied to sovereign issuers of ''other'' securities on a case-by-case basis. The Commission notes that there is a typographical error in NASD Rule 4420(f)(2), which the NASD, through its subsidiary, Nasdaq, will have to submit a filing, pursuant to the provisions of section 19(b) under the Act, to delete any reference to paragraph (e) under this Rule.

[10] NASD Rule 2310(b) requires members to make reasonable efforts to obtain information concerning a customer's financial status, a customer's tax status, the customer's investment objectives, and such other information used or considered to be reasonable by such member or registered representative in making recommendations to the customer.

[11] 15 U.S.C. 78*o*–3.

[12] 15 U.S.C. 78*o*–3(6).

[13] *See* note 7, *supra.*

[14] *See* Securities Exchange Act Release Nos. 47009 (December 16, 2002), 67 FR 78540 (December 24, 2002) (approving the listing and trading of Market Recovery Notes linked to the Nasdaq–100 Index); and 46883 (November 21, 2002), 67 FR 71216 (November 29, 2002) (approving the listing and trading of Market Recovery Notes linked to the Dow Jones Industrial Average).

section 15A(b)(6) of the Act [15] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest.[16] The Commission believes that the Notes will provide investors with a means to participate in any percentage increase in the Index that exist at the maturity of the Notes, subject to the Capped Value. Specifically, as described more fully above, if the value of the S&P 500 Index has increased, a beneficial owner will be entitled to receive at maturity a payment of the Notes based on triple the amount of any percentage increase in the S&P 500 Index, not to exceed the Capped Value.

The Notes are leveraged debts instruments whose price will be derived from and based upon the value of the Index. In addition, as discussed more fully above, the Notes do not guarantee any return of principal at maturity. Thus, if the S&P 500 Index has declined at maturity, a beneficial owner may receive significantly less than the original public offering price of the Notes.[17] Accordingly, the level of risk involved in the purchase or sale of the Notes is similar to the risk involved in the purchase or sale of traditional common stock. Because the final rate of return on the Notes is derivatively priced and based upon the performance of an index of securities, because the Notes are debt instruments that do not guarantee a return of principal, and because investors' potential return is limited by the Capped Value, there are several issues regarding trading of this type of product. For the reasons discussed below, the Commission believes that Nasdaq's proposal adequately addresses the concerns raised by this type of product.

First, the Commission notes that the protections of NASD Rule 4420(f) were designed to address the concerns attendant to the trading of hybrid securities like the Notes.[18] In particular, by imposing the hybrid listing standards, heightened suitability for recommendations,[19] and compliance requirements, noted above, the Commission believes that Nasdaq has adequately addressed the potential problems that could arise from the hybrid nature of the Notes. The Commission notes that Nasdaq will distribute a circular to its membership that provides guidance regarding member firm compliance responsibilities and requirements, including suitability recommendations, and highlights the special risks and characteristics associated with the Notes. Specifically, among other things, the circular will indicate that the Notes do not guarantee any return of principal at maturity, that the maximum return on the Notes is limited to $11.60 and $16 per unit,[20] that the Notes will not pay interest, and that the Notes will provide exposure in the Index. Distribution of the circular should help to ensure that only customers with an understanding of the risks attendant to the trading of the Notes and who are able to bear the financial risks associated with transactions in the Notes will trade the Notes. In addition, the Commission notes that Merrill Lynch will deliver a prospectus in connection with the initial purchase of the Notes.

Second, the Commission notes that the final rate of return on the Notes depends, in part, upon the individual credit of the issuer, Merrill Lynch. To some extent this credit risk is minimized by the NASD's listing standards in NASD Rule 4420(f), which provide that only issuers satisfying substantial asset and equity requirements may issue these types of hybrid securities. In addition, the NASD's hybrid listing standards further require that the Notes have at least $4 million in market value. Financial information regarding Merrill Lynch, in addition to information concerning the issuers of the securities comprising the S&P 500 Index, will be publicly available.[21]

Third, the Notes will be registered under section 12 of the Act. As noted above, the NASD's and Nasdaq's existing equity trading rules will apply to the Notes, which will be subject to equity margin rules and will trade during the regular equity trading hours of 9:30 a.m. to 4 p.m. NASD Regulation's surveillance procedures for the Notes will be the same as its current surveillance procedures for equity securities, and will include additional monitoring on key pricing dates.

Fourth, the Commission has a systemic concern that a broker-dealer, such as Merrill Lynch, or a subsidiary providing a hedge for the issuer will incur position exposure. However, as the Commission has concluded in previous approval orders for the hybrid instruments issued by broker-dealers, [22] the Commission believes that this concern is minimal given the size of the Notes issuance in relation to the net worth of Merrill Lynch.

Finally, the Commission believes that the listing and trading of the proposed Notes should not unduly impact the market for the securities underlying the Index or raise manipulative concerns. In approving the product, the Commission recognizes that the S&P 500 Index is a capitalization-weighted index of 500 companies listed on Nasdaq, the NYSE and the AMEX. The Commission notes that the Index is determined, composed, and calculated by Standard & Poor's. As of January 31, 2003, the aggregate market value of the 500 companies included in the Index represented approximately 79% of the aggregate market value of stocks included in the Standard & Poor's Stock Guidance Database of domestic common stocks traded in the U.S., excluding American depositary receipts, limited partnerships and mutual funds. Standard & Poor's chooses companies for inclusion in the Index with the aim of achieving a distribution by broad industry groupings that approximates the distribution of these groupings in the common stock population of the Standard & Poor's Stock Guide Database. Furthermore, as of February 18, 2003, ten main groups of companies comprise the Index with the percentage weight of the companies included in each group indicated in parentheses as follows: Consumer Discretionary (13.4%), Consumer Staples (9.4%),

[15] 15 U.S.C. 78*o*–3(b)(6).

[16] In approving the proposed rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[17] Any amount the beneficial owner would receive at maturity (which is less than the original offering price) would correspond to any decline in value of the S&P 500. Telephone conversation between John D. Nachmann, Senior Attorney, Nasdaq, and Florence E. Harmon, Senior Special Counsel, Division of Market Regulation (''Division''), Commission, on March 7, 2003.

[18] *See* 1993 Order, *supra* note 4.

[19] As discussed above, Nasdaq will advise members recommending a transaction in the Notes to: (1) Determine that the transaction is suitable for the customer; and (2) have a reasonable basis for believing that the customer can evaluate the special characteristics of, and is able to bear the financial risks of, the transaction.

[20] The actual Capped Value will be determined at the time of issuance of the Notes.

[21] The companies comprising the Index are reporting companies under the Act.

[22] *See, e.g.,* Securities Exchange Act Release Nos. 44913 (October 9, 2001), 66 FR 52469 (October 15, 2001) (order approving File No. SR–NASD–2001–73) (approving the listing and trading of notes issued by Morgan Stanley Dean Witter & Co. whose return is based on the performance of the Index); 44483 (June 27, 2001), 66 FR 35677 (July 6, 2001) (order approving File No. SR–Amex–2001–40) (approving the listing and trading of notes issued by Merrill Lynch whose return is based on a portfolio of 20 securities selected from the Amex Institutional Index); and 37744 (September 27, 1996), 61 FR 52480 (October 7, 1996) (order approving File No. SR–Amex–96–27) (approving the listing and trading of notes issued by Merrill Lynch whose return is based on a weighted portfolio of healthcare/biotechnology industry securities).

Energy (6.0%), Financials (20.6%), Health Care (15.3%), Industrials (11.3%), Information Technology (14.4%), Materials (2.8%), Telecommunication Services (4.0%), and Utilities (2.8%).

Given the large diversification, capitalization, and relative percentage weightings of the companies included in each group of companies comprising the Index, the Commission continues to believe, as it has concluded previously, that the listing and trading of securities that are linked to the S&P 500 Index, should not unduly impact the market for the underlying securities comprising the S&P 500 Index or raise manipulative concerns.[23] As discussed more fully above, the Commission also believes that the relative percentage weightings of the ten groups of companies comprising the Index should ensure that no one stock or group of stocks significantly minimize the potential for manipulation of the Index. Moreover, the issuers of the underlying securities comprising the S&P 500 Index, are subject to reporting requirements under the Act, and all of the component stocks are with listed on Nasdaq, the NYSE, or the Amex. In addition, Nasdaq's surveillance procedures should serve to deter as well as detect any potential manipulation.

The Commission finds good cause for approving the proposed rule change, as amended, prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register.** The Commission believes that the Notes will provide investors with an additional investment choice and that accelerated approval of the proposal will allow investors to begin trading the Notes promptly. In addition, the Commission notes that it has previously approved the listing and trading of similar Notes and other hybrid securities based on the S&P 500 Index.[24] Accordingly, the Commission believes that there is good cause, consistent with sections 15A(b)(6) and 19(b)(2) of the Act,[25] to approve the proposal, on an accelerated basis.

## V. Conclusion

It is therefore Ordered, pursuant to section 19(b)(2) of the Act,[26] that the proposed rule change (SR–NASD–2003–22) is hereby approved on an accelerated basis.

[23] *See* note 7, *supra.*

[24] *See* note 13, *supra.*

[25] 15 U.S.C. 78*o*–3(b)(6) and 78s(b)(2).

[26] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[27]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6071 Filed 3–12–03; 8:45 am]

**BILLING CODE 8010–01–P**

[27] 17 CFR 200.30–3(a)(12).

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47459; File No. SR–NASD–2002–124]**

## Self-Regulatory Organizations; Order Approving Proposed Rule Change, as Amended by Amendment No. 1 Thereto, by the National Association of Securities Dealers, Inc. Relating to Proposed Amendment to NASD Conduct Rule 2260 To Expand the Definition of ''Designated Investment Adviser'' To Include State Registered Investment Advisers for the Purpose of Receiving and Voting Proxy Materials on Behalf of Beneficial Owners

March 6, 2003.

On September 19, 2002, the National Association of Securities Dealers, Inc. (''NASD'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and rule 19b–4 thereunder,[2] a proposed rule change to amend NASD Conduct Rule 2260 to expand the definition of ''Designated Investment Adviser'' to include state registered investment advisers for the purpose of receiving and voting proxy materials on behalf of beneficial owners. On January 8, 2003, the NASD submitted Amendment No. 1 to the proposed rule change.[3]

The Commission published the proposed rule change, as amended, for comment in the **Federal Register** on January 27, 2003.[4] The Commission received one comment letter relating to the proposal.[5] This order approves the amended proposal.

Currently, NASD Conduct Rule 2260 requires members to forward proxy material, annual reports, information statements and other material sent to security holders to the beneficial owner or the beneficial owner's ''designated investment adviser.'' The rule defines a ''designated investment adviser'' as a person registered under the Investment Advisers Act of 1940 (''Advisers Act'') who exercises investment discretion pursuant to an advisory contract for the beneficial owner and is designated in writing by the beneficial owner to receive proxy and related materials and vote the proxy, and to receive annual reports and other material sent to security holders. The NASD represents that when the National Securities Markets Improvement Act was passed in 1996, and certain state registered investment advisers were no longer required to be registered under the Advisers Act, NASD Conduct Rule 2260 was not updated to account for this change. As a result, under the current rule, beneficial owners cannot designate state registered investment advisers to receive proxy and other materials. The proposed rule change would expand the definition of ''designated investment adviser'' to include persons registered by a state as an investment adviser.

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association[6] and, in particular, the requirements of section 15A of the Act.[7] The Commission finds that the proposed rule change is consistent with section 15A(b)(6) of the Act,[8] which requires, among other things, that the rules of a national securities association be designed to promote just and equitable principles of trade and, in general, to protect investors and the public interest. The Commission believes that amending NASD Conduct Rule 2260 to expand the definition of ''designated investment adviser'' to include persons registered by a state as an investment adviser, would allow for the reasonable

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Kosha K. Dalal, Assistant General Counsel, Regulatory Policy and Oversight, NASD, to Katherine England, Assistant Director, Division of Market Regulation, Commission, dated January 8, 2003 (''Amendment No. 1''). In Amendment No. 1, the NASD proposed to (1) revise the first footnote of proposed NASD Conduct Rule 2260 to define the term ''state'' by reference to the Investment Advisers Act of 1940, instead of the Securities Exchange Act of 1934, and (2) underline the text of two proposed footnotes in proposed NASD Conduct Rule 2260 to indicate that they are proposed new text.

[4] *See* Securities Exchange Act Release No. 47214 (January 17, 2003), 68 FR 3915.

[5] *See* letter from Christine A. Bruenn, NASSA President and Maine Securities Administrator, North American Securities Administrators Association, Inc. (''NASAA''), to Jonathan G. Katz, Secretary, Commission, dated February 18, 2003. In its comment letter, the NASAA expressed support for the proposal. *See also infra* note 9.

[6] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78*o*–3.

[8] 15 U.S.C. 78*o*–3(b)(6).

expectation that all registered advisers, either state or federal, subject to due authorization and regulation, be permitted to receive and vote proxy materials on their behalf. The Commission also believes that this change recognizes, and is consistent with, the regulatory scheme set up for the registration of investment advisors under state and federal law pursuant to Title III of the National Securities Markets Improvement Act of 1996 (the ''Coordination Act'').[9]

The rule will continue to require that a member that receives a written designation from a beneficial owner must ensure that the beneficial owner's designated investment adviser is registered under the Advisers Act or, for state registered investment advisers, is registered as an investment adviser under the laws of the state. Members must also continue to ensure that the designated investment adviser is exercising investment discretion pursuant to an advisory contract for the beneficial owner; and is designated in writing by the beneficial owner to receive and vote proxies for stock that is in the possession of the members. Nasdaq rules would also require members to keep records substantiating this information. These requirements should help to ensure that any state registered adviser is acting on behalf of the beneficial owner.

*It is therefore ordered,* pursuant to section 19(b)(2) of the Act,[10] that the proposed rule change (SR–NASD–2002–124), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6074 Filed 3–12–03; 8:45 am]

**BILLING CODE 8010–01–P**

[9] *See* NASAA Comment Letter, *supra* note 6. In its comment letter, the NASAA stated that while federal and state-registered advisers are distinguished based on their levels of assets under management, both federal and state-registered advisers generally perform similar functions. According to the NASAA, while not all clients may want their adviser to vote on their behalf, NASAA believes this option should be available to all investors.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47452; File No. SR–NYSE–2001–27]**

## Self-Regulatory Organizations; Order Approving Proposed Rule Change, as Amended by Amendment No. 1 Thereto, by the New York Stock Exchange, Inc. Relating to Amendments to Section 804 of the Listed Company Manual and Rule 499 of the Exchange

March 6, 2003.

### I. Introduction

On August 17, 2001, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Section 804 of the Listed Company Manual to specify that public directors will constitute a majority of the directors of the Committee for Review voting on final delisting determinations; and to codify this change in the parallel Exchange Rule 499, as well as make other minor conforming changes. On January 22, 2003, the NYSE filed Amendment No. 1 to the proposed rule change with the Commission.[3]

The Commission published the proposed rule change, as amended, for comment in the **Federal Register** on February 3, 2003.[4] No comments were received on the proposal. This order approves the amended proposal.

### II. Description of the Proposal

Section 804 of the Listed Company Manual describes the procedures to be followed when the Exchange determines that a security should be removed from the list. It provides that the issuer has a right to request a review of the Exchange's determination by a Committee of the Board of Directors of the Exchange, and currently specifies that that committee is to be ''comprised of a majority of public Directors.'' This requirement was added as part of a larger revision of these procedures that became effective in 2000.[5] The Committee for Review is the committee of the Board that reviews both disciplinary and delisting matters and, according to the NYSE, it has often been comprised of equal numbers of public and industry directors. According to the Exchange, in order to reconcile the majority of public Directors requirement with the Committee's traditional composition, and to allow all members of the Committee for Review present at a meeting to participate in discussions, the Committee required that the quorum for delisting matters include two public directors and one industry director. Consequently, a rotation system was established with respect to industry directors voting on delisting matters so that those voting were comprised of a majority of public directors and at least one industry director.[6]

The proposal amends section 804 of the Listed Company Manual to more accurately describe the Exchange's procedures. In addition, pursuant to the proposed rule change, the Chairman of the Committee would be required to disclose to the issuer and the staff at the commencement of each delisting hearing which of the industry directors will be voting on the delisting matter. Furthermore, the decision relating to the delisting appeal would be required to identify by name which directors participated only and which directors voted on the matter. The written decision issued by the Committee would also be required to clearly state that, in reaching its decision, the Committee considered only the oral arguments, written briefs and accompanying materials presented by the parties at the time of the hearing. The Exchange also proposes to codify these changes in the parallel Exchange Rule 499. Proposed NYSE Rule 499 also reflects a previous amendment to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Darla Stuckey, Corporate Secretary, NYSE, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated January 17, 2003 (''Amendment No. 1'').

[4] *See* Securities Exchange Act Release No. 47253 (January 24, 2003), 68 FR 5322.

[5] *See* Securities Exchange Act Release No. 42863 (May 30, 2000), 65 FR 36488 (June 8, 2000).

[6] Pursuant to the rotation system, the Committee designates prior to each delisting hearing which industry director(s) shall vote. At all hearings, all public directors present shall vote. For example, at a Committee meeting attended by three (3) public directors and three (3) industry directors at which two delisting appeals are considered, all public directors present and industry directors 1 and 2 will vote on the first delisting matter and all public directors present and industry directors 3 and 1 will vote on the second delisting matter. If, on the Committee's next review date, the meeting is attended by two (2) public directors and three (3) industry directors and one delisting appeal is considered, all public directors present and industry director 2 will vote on the matter; industry directors 1 and 3 will not vote. If any of the industry directors designated to vote next is not present at a Committee meeting, the next succeeding industry director(s) will vote. The rotation system is subject to the composition of the Committee, which varies at each meeting as described above, depending upon each director's availability. As is the case with other procedures of the Committee, the rotation system may also be changed from time to time.

section 804 of the Listed Company Manual that was inadvertently not added to NYSE Rule 499.

### III. Discussion

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] Specifically, the Commission believes the proposal is consistent with the section 6(b)(5)[8] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

The Commission believes that the proposal provides fair procedures for issuers appealing delisting determinations by continuing to ensure that a majority of the members voting on a delisting matter will be public directors and by clarifying that decisions will be based on the record developed by the parties. The Commission also believes that the proposal should add greater transparency to the process since the Chairman of the Committee would be required to disclose to the issuer and the staff at the commencement of each delisting hearing which of the industry directors will be voting on the delisting matter.

### IV. Conclusion

*It is therefore ordered,* pursuant to section 19(b)(2) of the Act,[9] that the proposed rule change (SR–NYSE–2001–27) is approved, as amended.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–5997 Filed 3–12–03; 8:45 am]

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[7] In approving this rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47463; File No. SR–NYSE–2002–44]**

## Self-Regulatory Organizations; Order Approving Proposed Rule Change and Amendment No. 1 Thereto by the New York Stock Exchange, Inc. Relating to Amendments to the Exchange's Automatic Execution Facility (NYSE Direct+)

March 7, 2003.

On September 9, 2002, the New York Stock Exchange (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Direct+ Rule 1000. The Exchange submitted an amendment to the proposed rule change on January 27, 2003.[3] On February 5, 2003, the rule proposal was published for comment in the **Federal Register**.[4] The Commission received no comments on the proposed rule change. This order approves the proposed rule change, as amended.

### I. Description of the Proposed Rule Change

The Exchange is proposing to amend its Direct+ pilot by amending NYSE Rule 1000. The NYSE Direct+ pilot expires on December 23, 2003.[5] This proposal would also expire with the pilot.[6] The NYSE proposes to amend NYSE Rule 1000(ii) to provide that Direct+ executions will not be available if the resulting trade would be more than five cents from the last sale. This would apply to any trade whether an auto-ex trade or a trade in the regular auction market. Any auto-ex order sent that would result in an execution more than five cents away from the last trade would be routed to the specialist as a SuperDOT limit order. The specialist would then represent that order as he or she would represent any other limit order received via the SuperDOT system.

Under the current provisions of NYSE Rule 1000, if the published quotation in a stock is gapped for a brief period of time, usually with one side or both of the quotation being set at 100 shares because of an influx of orders on one side of the market, or if the bid and/or offer size of the prevailing quotation is set at 100 shares, the Direct+ facility is not available. Under very active market conditions, the specialist may quote 100 shares bid or offered in order to allow trades in the auction market to be consummated without the last sale price being changed due to Direct+ executions. The Exchange has stated that this could result in the Exchange's disseminated quotation temporarily not reflecting the actual depth of the market for a stock as reflected by the dynamics of trading interest in the crowd. If the Direct+ facility is not available in instances where the actual spread in a stock's quotation is greater than five cents, the specialist will be able to show the actual depth in the market. According to the Exchange, if the actual spread resulting from bids and offers on the specialist's book, or resulting from trading crowd interest results in a spread of less than five cents from the price of the last trade, the specialist must display these, and Direct+ orders will remain eligible for automatic execution.

The Exchange also proposes to amend Rule 1000(v) to provide that the specialist during the process for completing a Rule 127 transaction should publish a bid and/or offer that is more than five cents away from the last reported transaction price (instead of a 100-share bid and/or offer) in the subject security on the Exchange. Any limit order that is received as the Rule 127 trade is being effected that would better the market represented by the broker's bid or offer on behalf of the NYSE Rule 127 cross trade would be included in the Rule 127 trade.

### II. Discussion

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] Specifically, the Commission believes the proposed rule change is consistent with Section 6(b)(5) of the Act,[8] which requires among other things, that the rules of the Exchange are

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Darla C. Stuckey, Corporate Secretary, NYSE, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, dated January 23, 2003 (''Amendment No. 1'').

[4] *See* Securities Exchange Act Release No. 47285 (January 29, 2003), 68 FR 5948.

[5] *See* Securities Exchange Act Release No. 46906 (November 25, 2002), 67 FR 72260 (December 4, 2002).

[6] Telephone call between Don Siemer, Director, Market Surveillance, NYSE, and Terri Evans, Assistant Director, Division of Market Regulation, Commission (March 5, 2003).

[7] The Commission has considered the proposed rule's impact on efficiency, competition and capital formation. 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and national market system, and, in general, to protect investors and the public interest.

The Commission believes that the proposed rule change should allow specialists to disseminate the actual depth of the NYSE auction market, while still ensuring that Direct+ is available when there is sufficient liquidity at prices closely related to the last sale.[9] The Commission also believes that the proposed rule change should continue to accommodate the crossing of block transactions outside the prevailing quote, at the same time ensuring that limit orders that are received while the block trade is being effected that improve the market represented by the broker-dealer's bid or offer on behalf of the Rule 127 trade will be executed as part of the block transaction.

## III. Conclusion

*It is therefore ordered,* pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change (SR–NYSE–2002–44) is approved as part of the NYSE Direct+ pilot that expires on December 23, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6070 Filed 3–12–03; 8:45 am]

BILLING CODE 8010–01–P

[9] According to the Exchange, a high percentage of executions in Direct+ occur within five cents of the last sale. *See* Amendment No. 1, *supra* note 3.

[10] *Id.*

[11] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47460; File No. SR–NYSE–2003–05]**

## Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change by the New York Stock Exchange, Inc. To Adopt, on a Permanent Basis, Margin Requirements for Security Futures Contracts

March 6, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on March 5, 2003, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to grant accelerated approval of the proposed rule change.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

This Exchange proposes to adopt, on a permanent basis, the amendments to NYSE Rule 431 relating to margin requirements for Security Futures Contracts (''SFCs''), which were approved by the SEC on a pilot basis for sixty days (the ''Pilot'') on November 7, 2002,[3] and the Pilot was extended for an additional sixty days, from January 6, 2003 until March 6, 2003.[4]

The Exchange believes that the proposed rule change would make its margin rule consistent with margin rules already adopted by the SEC and the Commodity Futures Trading Commission (''CFTC'') and those filed by other self-regulatory organizations (''SROs'') regarding security futures.

Specifically, the proposed amendments would: (1) Permit customer margining of SFCs, and establish initial and maintenance margin requirements for SFCs; (2) allow for initial and maintenance margin levels for offsetting positions involving SFCs and related positions at lower levels than would be required if margined separately; (3) provide for a Market Maker exclusion for proprietary trades of a Security Futures Dealer (''SFD'') and allow for ''good faith'' margin treatment for the accounts of approved options specialists, market makers and other specialists; (4) provide definitions relative to SFCs for application of this rule; (5) provide that SFCs transacted in a futures account shall not be subject to any provisions of Rule 431; (6) provide for money market mutual funds as defined under Rule 2a-7[5] of the ICA,[6] to be used to satisfy margin requirements for SFCs provided certain conditions are met; (7) require that SFCs transacted in a securities account be subject to all other provisions of NYSE Rule 431, particularly Rule 431(f)(8)(B) (''Day Trading''); and (8) permit members and member organizations for which the Exchange is the Designated Examining Authority (''DEA'') to participate in the trading of SFCs.

Below is the text of the proposed rule change. Proposed new language is italicized; proposed deletions are in brackets. In addition, the table of offsets is new rule language.

* * * * *

Rule 431 (''Margin Requirements'')

Rule 431. (a) For purposes of this Rule, the following terms shall have the meanings specified below:

(1) The term ''current market value'' means the total cost or net proceeds of a security on the day it was purchased or sold or at any other time the preceding business day's closing price as shown by any regularly published reporting or quotation service*, except for security futures contracts (see Section (f)(10)(C)(ii)).* If there is no closing price, a member organization may use a reasonable estimate of the market value of the security as of the close of business on the preceding business day.

Rule 431 (a)(2) through (a)(3) unchanged.

(4) The term ''equity'' means the customer's ownership interest in the account, computed by adding the current market value of all securities ''long'' and the amount of any credit balance and subtracting the current market value of all securities ''short'' and the amount of any debit balance. *Any variation settlement received or paid on a security futures contract shall be considered a credit or debit to the account for purposes of equity.*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 46782 (November 7, 2002), 67 FR 69052 (November 14, 2002) (SR–NYSE–2002–53).

[4] *See* Securities Exchange Act Release No. 47129 (January 3, 2003), 68 FR 2094 (January 15, 2003) (SR–NYSE–2003–01).

[5] 17 CFR 270.2a–7.

[6] 15 U.S.C. 80a *et seq.*

(5) The term ''exempted security'' or ''exempted securities'' has the meaning as in Section 3(a)(12) of the Securities Exchange Act of 1934 *(the ''Exchange Act'' or ''SEA'').*

(6) The term ''margin'' means the amount of equity to be maintained on a security position held or carried in an account.

(7) The term ''person'' has the meaning as in Section 3(a)(9) of the [Securities Exchange Act of 1934] *Exchange Act.*

(8) The term ''basket'' shall mean a group of stocks that the Exchange or any national securities exchange designates as eligible for execution in a single trade through its trading facilities and that consists of stocks whose inclusion and relative representation in the group are determined by the inclusion and relative representation of their current market prices in a widely-disseminated stock index reflecting the stock market as a whole.

Initial Margin

(b) For the purpose of effecting new securities transactions and commitments, the customer shall be required to deposit margin in cash and/or securities in the account which shall be at least the greater of:

(1) the amount specified in Regulation T of the Board of Governors of the Federal Reserve System *or Rules 400 through 406 of the Exchange Act or Rules 41.42 through 41.48 of The Commodity Exchange Act (''CEA''),* or

(2) the amount specified in section (c) of this Rule, or

(3) such greater amount as the Exchange may from time to time require for specific securities, or

(4) equity of at least $2,000 except that cash need not be deposited in excess of the cost of any security purchased (this equity and cost of purchase provision shall not apply to ''when distributed'' securities in a cash account). The minimum equity requirement for a ''pattern day trader'' is $25,000 pursuant to paragraph (f)(8)(B)(iv)(1) of this Rule. Withdrawals of cash or securities may be made from any account which has a debit balance, ''short'' position or commitments, provided it is in compliance with Regulation T of the Board of Governors of the Federal Reserve System *and Rules 400 through 406 of the Exchange Act and Rules 41.42 through 41.48 of the CEA* and after such withdrawal the equity in the account is at least the greater of $2,000 ($25,000 in the case of ''pattern day traders'') or an amount sufficient to meet the maintenance margin requirements of this Rule.

Maintenance Margin

(c) The margin which must be maintained in all accounts of customers, except for cash accounts subject to Regulation T unless a transaction in a cash account is subject to other provisions of this rule, shall be as follows:

(1) 25% of the current market value of all securities *except for security futures contracts,* ''long'' in the account; plus

(2) $2.50 per share or 100% of the current market value, whichever amount is greater, of each stock ''short'' in the account selling at less than $5.00 per share; plus

(3) $5.00 per share or 30% of the current market value, whichever amount is greater, of each stock ''short'' in the account selling at $5.00 per share or above; plus

(4) 5% of the principal amount or 30% of the current market value, whichever amount is greater, of each bond ''short'' in the account.

*(5) The minimum maintenance margin levels for security futures contracts, long and short, shall be 20% of the current market value of such contract. (See paragraph (f) of this Rule for other provisions pertaining to security futures contracts.)*

Rule 431(d) through (e)(5) unchanged.

(e)(6)(A) Broker/Dealer Accounts.—A member organization may carry the proprietary account of another broker/dealer, which is registered with the Securities and Exchange Commission, upon a margin basis which is satisfactory to both parties, provided the requirements of Regulation T of the Board of Governors of the Federal Reserve System *and Rules 400 through 406 under the Exchange Act and Rules 41.42 through 41.48 under the CEA* are adhered to and the account is not carried in a deficit equity condition. The amount of any deficiency between the equity maintained in the account and the haircut requirements pursuant to SEA Rule 15c3–1 (Net Capital) shall be deducted in computing the Net Capital of the member organization under the Exchange's Capital Requirements. However, when computing Net Capital deductions for transactions in securities covered by paragraphs (e)(2)(F) and (e)(2)(G) of this Rule, the respective requirements of those paragraphs may be used, rather than the haircut requirements of SEA Rule 15c3–1.

Rule 431(e)(6)(B) unchanged.

(e)(7) Nonpurpose Credit—In a nonsecurities credit account, a member organization may extend and maintain nonpurpose credit to or for any customer without collateral or on any collateral whatever, provided:

(A) the account is recorded separately and confined to the transactions and relations specifically authorized by Regulation T of the Board of Governors of the Federal Reserve System;

(B) the account is not used in any way for the purpose of evading or circumventing any regulation of the Exchange or of the Board of Governors of the Federal Reserve System *and Rules 400 through 406 under the Exchange Act and Rules 41.42 through 41.48 under the CEA;* and

(C) the amount of any deficiency between the equity in the account and the margin required by the other provisions of this Rule shall be deducted by computing the Net Capital of the member organization under the Exchange's Capital Requirements. (The term ''nonpurpose credit'' means an extension of credit other than ''purpose credit,'' as defined in Section 220.2 of Regulation T of the Board of Governors of the Federal Reserve System.)

Rule 431(e)(8) through (f)(9) unchanged.

(f)

*(10) Customer Margin Rules Relating to Security Futures.*

*(A) Applicability. No member or member organization may effect a transaction involving, or carry an account containing, a security futures contract with or for a customer in a margin account, without obtaining proper and adequate margin as set forth in this section.*

*(B) Amount of customer margin.*

*(i) General Rule. As set forth in sections (b) and (c) of this Rule, the minimum initial and maintenance margin levels for each security futures contract, long and short, shall be twenty (20) percent of the current market value of such contract.*

*(ii) Excluded from the rules' requirements are arrangements between a member or member organization and a customer with respect to the customer's financing of proprietary positions in security futures, based on the member's or member organization's good faith determination that the customer is an ''Exempted Person'', as defined in Rule 401(a)(9) under the Exchange Act, and Rule 41.43(a)(9) of the CEA, except for the proprietary account of a broker-dealer carried by a member organization pursuant to Section (e)(6)(A) of this Rule. Once a registered broker or dealer, or member of a national securities exchange ceases to qualify as an exempted person, it shall notify the member or member organization of this fact before establishing any new security futures positions. Any new security futures*

*positions will be subject to the provisions of this part.*

*(iii) Permissible Offsets.—Notwithstanding the minimum margin levels specified in paragraph (f)(10)(B)(i) of this Rule, customers with offset positions involving security futures and related positions may have initial or maintenance margin levels (pursuant to the offset table below) that are lower than the levels specified in paragraph (f)(10)(B)(i) of this Rule.*

| Description of offset | Security underlying the security future | Initial margin requirement | Maintenance margin requirement |
|---|---|---|---|
| 1. Long security future (or basket of security futures representing each component of a narrow-based securities index) *and* long put option on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus pay for the long put in full. | The lower of: (1) 10% of the aggregate exercise price of the put plus the aggregate put out-of-the-money amount, if any; or (2) 20% of the current market value of the long security future. |
| 2. Short security future (or basket of security futures representing each component of a narrow-based securities index) *and* short put option on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the short security future, plus the aggregate put in-the-money amount, if any. Proceeds from the put sale may be applied. | 20% of the current market value of the short security future, plus the aggregate put in-the-money amount, if any. |
| 3. Long security future *and* Short position in the same security (or securities basket) underlying the security future. | Individual stock or narrow-based security index. | The initial margin required under Regulation T for the short stock or stocks. | 5% of the current market value as defined in Regulation T of the stock or stocks underlying the security future. |
| 4. Long security future (or basket of security futures representing each component of a narrow-based securities index) *and* short call option on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any. Proceeds from the call sale may be applied. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any. |
| 5. Long a basket of narrow-based security futures that together tracks a broad based index *and* short a broad-based security index call option contract on the same index. | Narrow-based security index. | 20% of the current market value of the long basket of narrow-based security futures, plus the aggregate call in-the-money amount, if any. Proceeds from the call sale may be applied. | 20% of the current market value of the long basket of narrow-based security futures, plus the aggregate call in-the-money amount, if any. |
| 6. Short a basket of narrow-based security futures that together tracks a broad-based security index *and* short a broad-based security index put option contract on the same index. | Narrow-based security index. | 20% of the current market value of the short basket of narrow-based security futures, plus the aggregate put in-the-money amount, if any Proceeds from the put sale may be applied. | 20% of the current market value of the short basket of narrow-based security futures, plus the aggregate put in-the-money amount, if any. |
| 7. Long a basket of narrow-based security futures that together tracks a broad-based security index *and* long a broad-based security index put option contract the same index. | Narrow-based security index. | 20% of the current market value of the long basket of narrow-based security futures, plus pay for the long put in full. | The lower of: (1) 10% of the aggregate exercise price of the put, plus the aggregate put out-of-the-money amount, if any; or (2) 20% of the current market value of the long basket of security futures. |
| 8. Short a basket of narrow-based security futures that together tracks a broad-based security index *and* long a broad-based security index call option contract on the same index. | Narrow-based security index. | 20% of the current market value of the short basket of narrow-based security futures, plus pay for the long call in full. | The lower of: (1) 10% of the aggregate exercise price of the call, plus the aggregate call out-of-the-money amount, if any: or (2) 20% of the current market value of the short basket of security futures. |
| 9. Long security future *and* short security future on the same underlying security (or index). | Individual stock or narrow-based security index. | The greater of: (1) 5% of the current market value of the long security future; or (2) 5% of the current market value of the short security future. | The greater of: 5% of the current market value of the long security future; or (2) 5% of the current market value of the short security future. |
| 10. Long security future, long put option *and* short call option. The long security future, long put and short call must be on the same underlying security and the put and call must have the same exercise price. (Conversion). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any, plus pay for the put in full. Proceeds from the call sale may be applied. | 10% of the aggregate exercise price, plus the aggregate call in-the-money amount, if any. |
| 11. Long security future, long put option *and* short call option. The long security future, long put and short call must be on the same underlying security and the put exercise price must be below the call exercise price (Collar). | Individual stock or narrow-based security index. | 20% of the current market value of the long security future, plus the aggregate call in-the-money amount, if any, plus pay for the put in full. Proceeds from call sale may be applied. | The lower of: (1) 10% of the aggregate exercise price of the put plus the aggregate put out-of-the-money amount, if any; or (2) 20% of the aggregate exercise price of the call, plus the aggregate call in-the-money amount, if any. |

| Description of offset | Security underlying the security future | Initial margin requirement | Maintenance margin requirement |
|---|---|---|---|
| 12. Short security future *and* long position in the same security (or securities basket) underlying the security future. | Individual stock or narrow-based security index. | The initial margin required under Regulation T for the long security or securities. | 5% of the current market value, as defined in Regulation T, of the long stock or stocks. |
| 13. Short security future *and* long position in a security immediately convertible into the same security underlying the security future, without restriction, including the payment of money. | Individual stock or narrow-based security index. | The initial margin required under Regulation T for the long security or securities. | 10% of the current market value, as defined in Regulation T, of the long stock or stocks. |
| 14. Short security future (*or* basket of security futures representing each component of a narrow-based securities index) *and* Long call option or warrant on the same underlying security (or index). | Individual stock or narrow-based security index. | 20% of the current market value of the short security future, plus pay for the call in full. | The lower of: (1) 10% of the aggregate exercise price of the call, plus the aggregate call out-of-the-money amount, if any; or (2) 20% of the current market value of the short security future. |
| 15. Short security future, short put option and long call option. The short security future, short put and long call must be on the same underlying security and the put and call must have the same exercise price. (Reverse Conversion). | Individual stock or narrow-based security index. | 20% of the current market value of the short security future, plus the aggregate put in-the-money amount, if any, plus pay for the call in full. Proceeds from put sale may be applied. | 10% of the aggregate exercise price, plus the aggregate put in-the-money amount, if any. |
| 16. Long (short) a security future *and* short (long) an identical security future traded on a different market. | Individual stock and narrow-based security index. | The greater of: (1) 3% of the current market value of the long security future(s); or (2) 3% of the current market value of the short security future(s). | The greater of: (1) 3% of the current market value of the short security future(s); or (2) 3% of the current market value of the short security future(s). |
| 17. Long (short) a basket of security futures that together tracks a narrow-based index and short (long) a narrow based index future. | Individual stock and narrow-based security index. | The greater of: (1) 5% of the current market value of the short security future(s); or (2) 5% of the current market value of the short security future(s). | The greater of: (1) 5% of the current market value of the short security future(s); or (2) 5% of the current market value of the short security future(s). |

[7] Two security futures contracts will be considered ''identical'' for this purpose if they are issued by the same clearing agency or cleared and contracts guaranteed by the same derivatives clearing organization, have identical specifications, and would offset each other at the clearing level.

*(C) Definitions. For the purposes of section (f)(10) of this Rule and the offset table noted above, with respect to the term ''security futures contracts,'' the following terms shall have the meanings specified below:*

*(i) The term ''security futures contract'' means a ''security future'' as defined in Section 3(a)(55) of the Exchange Act.*

*(ii) The term ''current market value'' has the same meaning as it is as defined in Rule 401(4) under the Exchange Act and Rule 41.43(a)(4) of the CEA.*

*(iii) The term ''underlying security'' means, in the case of physically settled security futures contracts, the security that is delivered upon expiration of the contract, and, in the case of cash settled security futures contracts, the security or securities index the price or level of which determines the final settlement price for the security futures contract upon its expiration.*

*(iv) The term ''underlying basket'' means, in the case of a securities index, a group of security futures contracts where the underlying securities as defined in paragraph (iii) above include each of the component securities of the applicable index and which meets the following conditions: (1) the quantity of each underlying security is proportional to its representation in the index, (2) the total market value of the underlying securities is equal to the aggregate value of the applicable index, (3) the basket cannot be used to offset more than the number of contracts or warrants represented by its total market value, and (4) the security futures contracts shall be unavailable to support any other contract or warrant transaction in the account.*

*(v) The term ''underlying stock basket'' means a group of securities which includes each of the component securities of the applicable index and which meets the following conditions: (1) the quantity of each stock in the basket is proportional to its representation in the index, (2) the total market value of the basket is equal to the underlying index value of the index options or warrants to be covered (3) the securities in the basket cannot be used to cover more than the number of index options or warrants represented by that value, and (4) the securities in the basket shall be unavailable to support any other option or warrant transaction in the account.*

*(vi) The term ''variation settlement'' has the same meaning as it is defined in Rule 401(a) of the Exchange Act and Rule 41.43(a)(32) of the CEA.*

*(D) Security Futures Dealers' Accounts. Notwithstanding the other provisions of this section (f)(10), a member organization may carry and clear the market maker permitted offset positions (as defined below) of one or more security future dealers in an account which is limited to market maker transactions, upon a ''Good Faith'' margin basis which is satisfactory to the concerned parties, provided the ''Good Faith'' margin requirement is not less than the Net Capital haircut deduction of the member organization carrying the transaction pursuant to Rule 325. In lieu of collecting the ''Good Faith'' margin requirement, a carrying member organization may elect to deduct in computing its Net Capital the amount of any deficiency between the equity maintained in the account and the ''Good Faith'' margin required.*

*For the purpose of this paragraph (f)(10)(D), the term ''security futures dealer'' means (1) a member or member organization of a national securities*

*exchange or a national securities association registered pursuant to Section 15A(a) of the Exchange Act; (2) is registered with such exchange or such association as a security futures dealer pursuant to rules that are effective in accordance with Section 19(b)(2) of the Exchange Act and, as applicable, Section 5c(c) of the CEA, that: (1) requires such member or member organization to be registered as a floor trader or a floor broker with the CFTC under Section 4f(a)(1) of the CEA, or as a dealer with the Commission under Section 15(b) of the Exchange Act; (2) or requires such member or member organization to maintain records sufficient to prove compliance with the rules of the exchange or association of which it is a member; (3) requires such member or member organization to hold itself out as being willing to buy and sell security futures for its own account on a regular and continuous basis; and (4) provides for disciplinary action, including revocation of such member's or member organization's registration as a security futures dealer, for such member's or member organization's failure to comply with Rules 400 through 406 of the Exchange Act and Rules 41.42 through 41.49 of the CEA or the rules of the exchange or association of which the security futures dealer is a member or member organization.*

*For purposes of this paragraph (f)(10)(D), a permitted offset position means in the case of a security futures contract in which a security futures dealer makes a market, a position in the underlying asset or other related assets, or positions in options overlying the asset or other related assets. Accordingly, a security futures dealer may establish a long or short position in the assets underlying the security futures contracts in which the security futures dealer makes a market, and may purchase or write options overlying those assets, if the account holds the following permitted offset positions:*

*(i) A long position in the security futures contract or underlying asset offset by a short option position which is ''in or at the money;''*

*(ii) A short position in the security futures contract or underlying asset offset by a long option position which is ''in or at the money;''*

*(iii) A position in the underlying asset resulting from the assignment of a market-maker short option position or making delivery in respect of a short security futures contract;*

*(iv) A position in the underlying asset resulting from the assignment of a market-maker long option position or taking delivery in respect of a long security futures contract;*

*(v) A net long position in a security futures contract in which a security futures dealer makes a market or the underlying asset;*

*(vi) A net short position in a security future contract in which a security futures dealer makes a market or the underlying asset; or*

*(vii) An offset position as defined in SEA Rule 15c3–1, including its appendices, or any applicable SEC staff interpretation or no-action position.*

*(E) Approved Options Specialists' or Market Makers' Accounts. Notwithstanding the other provisions of (f)(10) and (f)(2)(j), a member organization may carry and clear the market maker permitted offset positions (as defined below) of one or more approved options specialists or market makers in an account which is limited to approved options specialist or market maker transactions, upon a ''Good Faith'' margin basis which is satisfactory to the concerned parties, provided the ''Good Faith'' margin requirement is not less than the Net Capital haircut deduction of the member organization carrying the transaction pursuant to Rule 325. In lieu of collecting the ''Good Faith'' margin requirement, a carrying member organization may elect to deduct in computing its Net Capital the amount of any deficiency between the equity maintained in the account and the ''Good Faith'' margin required. For the purpose of this paragraph (f)(10)(E), the term ''approved options specialist or market maker'' means a specialist, market maker, or registered trader in options as referenced in paragraph (f)(2)(j) of this Rule, who is deemed a specialist for all purposes under the Exchange Act and who is registered pursuant to the rules of a national securities exchange.*

*For purposes of this paragraph (f)(10)(E), a permitted offset position means a position in the underlying asset or other related assets. Accordingly, a specialist or market maker may establish a long or short position in the assets underlying the options in which the specialist or market maker makes a market, or a security futures contract thereon, if the account holds the following permitted offset positions:*

*(i) A long position in the underlying instrument or security futures contract offset by a short option position which is ''in or at the money;''*

*(ii) A short position in the underlying instrument or security futures contracts offset by a long option position which is ''in or at the money;''*

*(iii) A stock position resulting from the assignment of a market maker short option position or delivery in respect of a short security futures contract;*

*(iv) A stock position resulting from the exercise of a market maker long option position or taking delivery in respect of a long security futures contract;*

*(v) A net long position in a security (other than an option) in which a market maker makes a market;*

*(vi) A net short position in a security (other than an option) in which the market maker makes a market; or*

*(vii) An offset position as defined in SEC Rule 15c3–1, including the appendices, or any applicable SEC staff interpretation or no-action position.*

*For purposes of paragraphs (f)(10)(D) and (E), the term ''in or at the money'' means the current market price of the underlying security is not more than the two standard exercise intervals below (with respect to a call option) or above (with respect to a put option) the exercise price of the option; the term ''in the money'' means the current market price of the underlying asset or index is not below (with respect to a call option) or above (with respect to a put option) the exercise price of the option; and the term ''overlying option'' means a put option purchased or a call option written against a long position in an underlying asset; or a call option purchased or a put option written against a short position in an underlying asset.*

*Securities, including options and security futures contracts, in such accounts shall be valued conservatively in the light of current market prices and the amount which might be realized upon liquidation. Substantial additional margin must be required or excess Net Capital maintained in all cases where the securities carried: (i) Are subject to unusually rapid or violent changes in value including volatility in the expiration months of options or security futures products, (ii) do not have an active market, or (iii) in one or more or all accounts, including proprietary accounts combined, are such that they cannot be liquidated promptly or represent undue concentration of risk in view of the carrying member or member organization's Net Capital and its overall exposure to material loss.*

*(F) Approved Specialists' Accounts—others. Notwithstanding the other provisions of (f)(10) and (f)(2)(j), a member organization may carry the account of an ''approved specialist,'' which account is limited to specialist transactions including hedge transactions with security futures contracts upon a margin basis which is satisfactory to both parties. The amount of any deficiency between the equity in the account and haircut requirements*

*pursuant to SEA Rule 15c3–1 (Net Capital) shall be deducted in computing the Net Capital of the member organization under the Exchange's Capital Requirements. For purposes of this paragraph (f)(10)(F) the term ''approved specialist'' means a specialist who is deemed a specialist for all purposes under the Exchange Act and who is registered pursuant to the rules of a national securities exchange.*

*.70 Money market mutual funds, as defined under Rule 2a-7 of the Investment Company Act of 1940, can be used for satisfying margin requirements under this subsection (f)(10), provided that the requirements of Rule 404(b) of the Exchange Act and Rule 46(b)(2) under the CEA are satisfied.*

*.80 Day-trading of security futures is subject to the minimum requirements of this Rule. If deemed a pattern day-trader, the customer must maintain equity of $25,000. The 20% requirement, for security futures contracts, should be calculated based on the greater of the initial or closing transaction and any amount exceeding NYSE excess must be collected. The creation of a customer call subjects the account to all the restrictions contained in Rule 431(f)(8)(B).*

*.90 The use of the ''time and tick'' method is based on the member's or member organization's ability to substantiate the validity of the system used. Lacking this ability dictates the use of the aggregate method.*

*.100 Security futures contracts transacted or held in a futures account shall not be subject to any provision of this Rule.*

* * * * *

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in Sections A, B, and C below.

### *A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to make permanent the amendments to NYSE Rule 431 regarding margin requirements for SFCs. The original proposed rule change to amend NYSE Rule 431 was approved by the Commission on a pilot basis for sixty days on November 7, 2002.[8] On January 6, 2003, the Commission approved an extension to the Pilot for an additional sixty days, ending March 6, 2003.[9]

The proposed amendments are being made to make the Exchange's margin rule consistent with margin rules already adopted by the SEC and the CFTC and those filed by other SROs regarding security futures.

Specifically, the proposed amendments would: (1) Permit customer margining of SFCs, and establish initial and maintenance margin requirements for SFCs; (2) allow for initial and maintenance margin levels for offsetting positions involving SFCs and related positions at lower levels than would be required if margined separately; (3) provide for a Market Maker exclusion for proprietary trades of a SFD and allow for ''good faith'' margin treatment for the accounts of approved options specialists, market makers and other specialists; (4) provide definitions relative to SFCs for application of this rule; (5) provide that SFCs transacted in a futures account shall not be subject to any provisions of NYSE Rule 431; (6) provide for money market mutual funds, as defined under Rule 2a–7[10] of the Investment Company Act of 1940,[11] to be used to satisfy margin requirements for SFCs provided certain conditions are met; (7) require that SFCs transacted in a securities account be subject to all other provisions of NYSE Rule 431, particularly Rule 431(f)(8)(B) (''Day Trading''); and (8) permit members and member organizations for which the Exchange is the DEA to participate in the trading of SFCs.

Background

The CFTC and SEC have adopted customer margin requirements for the trading of SFCs (''SEC/CFTC Margin Regulations'')[12] pursuant to authority delegated to them by the Federal Reserve Board (''FRB'') under section 7(c)(2)(B) of the Act.[13] As noted in the adopting release,[14] new subsection (2) to section 7(c) provides that the customer margin requirements for SFCs must satisfy four requirements: (1) They must preserve the financial integrity of markets trading security futures products; (2) they must prevent systemic risk; (3) they must (a) be consistent with the margin requirements for comparable options traded on an exchange registered pursuant to section 6(a) of the Exchange Act,[15] and (b) provide for initial and maintenance margin that are not lower than the lowest level of margin, exclusive of premium, required for comparable exchange traded options; and (4) they must be and remain consistent with the margin requirements established by the FRB under Regulation T.[16] The regulations on customer margin for security futures became effective on September 13, 2002. Pursuant to these amendments the Exchange filed proposed amendments to NYSE Rule 431, which were approved temporarily on a pilot basis by the Commission.

Specifically, on October 23, 2002, the Exchange filed a proposed rule change with the Commission to amend NYSE Rule 431 with regard to SFCs.[17] On November 6, 2002, the Exchange filed Amendment No. 1 to the proposed rule change.[18] The proposed rule change was approved by the Commission as a sixty-day pilot on November 7, 2002,[19] effective through January 6, 2003 (''Pilot'').

Among the amendments approved, as part of the Pilot, was new NYSE Rule 431(f)(10) (''Customer Margin Rules Relating to Security Futures''), which provides that SFCs transacted in a securities account be subject to all other provisions of NYSE Rule 431, including Rule 431(f)(8)(B) (''Day Trading'').

Also approved as part of the Pilot were NYSE Rule 431(f)(10)(D) (''Security Futures Dealers'' Accounts''), Rule 431(f)(10)(E) (''Approved Options Specialists' or Market Makers' Accounts''), and Rule 431(f)(D)(F) (''Approved Specialists'' Accounts-others''). The rule permits ''good faith'' margin treatment for specified hedged offset positions carried in the accounts noted above. However, unlike the SFD rules of other SROs,[20] the Exchange's

[8] *See supra* note 3.

[9] *See supra* note 4.

[10] 17 CFR 270.2a–7.

[11] 15 U.S.C. 80a *et seq.*

[12] 17 CFR 240.400 through 406; 17 CFR 41.41 through 41.48.

[13] 15 U.S.C. 78g(c)(2)(B).

[14] *See* Securities Exchange Act Release No. 46292 (August 1, 2002), 67 FR 53146 (August 14, 2002).

[15] 15 U.S.C. 78f.

[16] 12 CFR part 220.

[17] *See* SR–NYSE–2002–53.

[18] *See* letter from Darla C. Stuckey, Corporate Secretary, NYSE, to Nancy Sanow, Assistant Director, Division, Commission, dated November 5, 2002 (''Amendment No. 1''). Amendment No. 1 replaced the original rule filing in its entirety (SR–NYSE–2002–53). Amendment No. 1 also proposed that the proposal be effective for a sixty-day pilot and requested accelerated approval of the proposed rule change.

[19] *See* Securities Exchange Act Release No. 46782 (November 7, 2002), 67 FR 69052 (November 14, 2002) (SR–NYSE–2002–53).

[20] *See e.g.*, Securities Exchange Act Release No. 46555 (September 26, 2002), 67 FR 61707 (October 1, 2002) (SR–OC–2002–01).

Pilot permitted member organizations to accord offset treatment in accounts carried for such specialists, market makers and SFDs only when their activity is limited to bona fide specialist or market making transactions. The limitations imposed were consistent with the Exchange's belief that market makers bear the primary responsibility and obligation to maintain fair and orderly markets, and provide liquidity to the marketplace.

On January 3, 2003, the Exchange filed a proposed rule change to extend the Pilot for an additional sixty days (from January 6, 2003 until March 6, 2003) to allow the Pilot to continue in effect on an uninterrupted basis and to permit customers to continue trading SFCs in securities accounts while the Exchange considered the comments discussed below that it had received on the Pilot.[21]

Discussion of Comments Received

On December 9, 2002, the Chicago Board Options Exchange, Incorporated (''CBOE'') submitted a comment letter with regard to the Exchange's margin rules for SFCs.[22] In its letter, the CBOE requested that the Commission not grant permanent approval of the amendments to NYSE Rule 431 as proposed and approved on a pilot basis, unless the Exchange amended the rule to exempt SFCs from its day trading provisions and deleted references to the term ''bona fide'' in connection with market maker or specialist transactions.

In addition, as proposed, the Exchange's day trading margin requirements would apply to SFCs carried in securities accounts. The CBOE believed that day trading provisions should not apply to such accounts because it would create a disparity that the CFMA was designed to eliminate. In this regard, CBOE's letter stated that the SEC and CFTC did not impose day trading margin requirements to SFCs carried in futures and securities accounts. Since similar margin rules recently approved by the Commission do not impose day trading margin requirements on SFCs carried in futures account, the CBOE stated that permanent approval of the Exchange's proposed rule would lead to a regulatory disparity the CFMA was designed to prevent.

The Exchange is now seeking to adopt, on a permanent basis, margin requirements for SFCs carried in securities accounts, with proposed text modifications from the Pilot based on the comments received and as discussed below.

In proposing its rule amendment on the application of day trading margin requirements to SFCs carried in securities accounts, the Exchange did not intend to create a regulatory disparity with other SROs' rules. However, the Exchange notes that an SRO's rules can be more stringent than those of the Commission. In proposing rules, the Exchange is guided by Commission rules and has latitude to promulgate more stringent rules, which it believes are necessary for the protection of investors. In this regard, NYSE believes that the application of the day trading margin requirements of NYSE Rule 431 as applied to SFCs carried in a securities account is consistent with the treatment of all securities transacted in a margin account under this rule. Accordingly, the Exchange will propose to apply the day trading margin requirements to SFCs carried in a securities account.

The CBOE also believes that the Exchange should delete the term ''bona fide'' in connection with market maker or specialist transactions. CBOE commented that the Exchange does not define the term ''bona fide'' nor does it use the term in relation to the other provisions of its margin rule relating to market maker and specialist transactions.

In response to CBOE's comments, the Exchange is proposing to amend the rule text by deleting the term ''bona fide'' in connection with specialist or market maker transactions. In proposing such language under the pilot program, it was the Exchange's intent to permit good faith margin treatment for offsetting positions that were effected by specialists or market makers in discharging the primary responsibilities noted above in its original filing, rather than to permit persons other than qualified market makers to act in such a capacity—hence the term ''bona fide'' in connection with specialist and market making transactions. Upon consideration, and in order to be consistent with similar rules proposed by other SROs,[23] the Exchange will not use the term ''bona fide'' in connection with specialist and market making transactions and instead the Exchange proposes to incorporate the definition of a SFD in Exchange Act Rule 400(c)(2)(v)[24] to clarify what constitutes a SFD for purpose of the rule. Notwithstanding this amendment, the Exchange reiterates that good faith margin treatment be permitted for transactions effected by SFDs in discharging their responsibilities and obligations to maintain fair and orderly markets, and to provide liquidity to the marketplace.

2. Statutory Basis

The basis under the Exchange Act for this proposed rule change is section 6(b)(5) of the Act,[25] which requires, among other things, that an exchange have rules that are designed to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. The Exchange believes that the proposed rule change is designed to accomplish these goals by permitting customers to trade SFCs in securities accounts.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

The Exchange notes that it received written comments on the original proposed rule change that was filed with the Commission on October 23, 2002, and thereafter amended on November 6, 2002. The Exchange has responded to such comments, and hereby amends its proposed rule change, which was approved by the Commission as a pilot program.

**III. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

[21] *See supra* note .

[22] *See* letter from Edward J. Joyce, President and Chief Operating Officer, CBOE, to Jonathan G. Katz, Secretary, Commission, dated December 9, 2002.

[23] *See e.g.,* Securities Exchange Act Release No. 46711 (November 5, 2002), 67 FR 68710 (November 12, 2002).

[24] 17 CFR 240.400(c)(2)(v).

[25] 15 U.S.C. 78f(b)(5).

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR–NYSE–2003–05 and should be submitted by April 3, 2003.

## IV. Commission Findings and Order Granting Accelerated Approval of a Proposed Rule Change

The NYSE has asked that the Commission approve the proposed rule change prior to the thirtieth day after publication of notice of the filing in the **Federal Register** to accommodate the continuance of trading of security futures in securities accounts pursuant to NYSE Rule 431 on an uninterrupted basis after the Pilot ends on March 6, 2003. The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[26] In particular, the Commission believes that the proposed rule change is consistent with the requirements of section 6(b)(5) of the Act,[27] which requires, among other things, that the rules of the Exchange be designed to promote just and equitable principles of trade and, in general, to protect investors and the public interest.[28] In addition, the Commission believes that the proposed rule change is consistent with section 7(c)(2)(B) of the Act,[29] which provides, among other things, that the margin requirements for security futures must preserve the financial integrity of markets trading security futures, prevent systemic risk, be consistent with the margin requirements for comparable exchange-traded options, and provide that the margin levels for security futures may be no lower than the lowest level of margin, exclusive of premium, required for any comparable exchange-traded option.

The Commission believes that the rule change is generally consistent with the customer margin rules for security futures adopted by the Commission and the CFTC. In particular, the Commission notes that, consistent with Rule 403 under the Act, NYSE's proposed rule provides for a minimum margin level of 20% of current market value for all positions in security futures carried in a securities account. The Commission believes that 20% is the minimum margin level necessary to satisfy the requirements of section 7(c)(2)(B) of the Act. Rule 403 under the Act[30] also provides that a national securities exchange may set margin levels lower than 20% of the current market value of the security future for an offsetting position involving security futures and related positions, provided that an exchange's margin levels for offsetting positions meet the criteria set forth in section 7(c)(2)(B) of the Act. The offsets proposed by NYSE are consistent with the strategy-based offsets permitted for comparable offset positions involving exchange-traded options and therefore consistent with section 7(c)(2)(B) of the Act.

In addition, the Commission believes it is consistent with the Act for the NYSE to exclude from its margin requirements positions in SFCs carried in a futures account. The Commission believes that by choosing to exclude such positions from the scope of Rule 431, the NYSE's proposal will make compliance by members with the regulatory requirements of several SROs easier. Moreover, as proposed, NYSE member organizations will accord ''good faith'' margin treatment to specified offsetting positions involving security futures, carried in a securities account for a SFD, consistent with the customer margin rules for security futures adopted by the Commission and the CFTC.

After careful consideration of the commenter's concern about applying the NYSE's day trading margin requirements to SFCs, the Commission believes that it is reasonable for the NYSE to impose day trading margin requirements on its members with respect to SFCs carried in a securities account. As NYSE noted, an SRO may adopt more stringent requirements than those promulgated by the Commission.

The Commission has also carefully considered the commenter's concern of using the term ''bona fide'' with respect to market maker or specialist transactions. The Commission notes that NYSE has deleted the term ''bona fide'' in reference to market maker or specialist transactions, and instead is incorporating the definition of an SFD in Rule 400(c)(2)(v) under the Act. The Commission believes that if it finds, in approving an SRO's rules for SFDs, that such rules are consistent with the definition of SFD in Rule 400(c)(2)(v), those rules would also be consistent with NYSE Rule 431(f)(10)(D). Therefore, the Commission believes this amendment should address the commenter's concerns that NYSE not impose a higher standard on transactions by market maker and specialist registered pursuant to rules of another SRO to qualify for favorable margin treatment.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register**. The Commission believes that accelerated approval of the proposed rule change should enable NYSE members to continue to trade SFCs in securities accounts on an uninterrupted basis. In addition, the Commission believes that granting accelerated approval to the proposed rule change should clarify NYSE members' obligations under NYSE Rule 431 with respect to their trading in SFCs. The Commission notes it approved NYSE's original filing as a temporary pilot to give members of the public an opportunity to comment on the substance of the proposed rule change before it requests permanent approval. The NYSE has responded to the comments received, as described above. Accordingly, the Commission finds good cause, consistent with section 19(b)(2) of the Act, to approve the proposed rule change prior to the thirtieth day after publication if the notice of filing.

## V. Conclusion

*It is therefore ordered,* pursuant to section 19(b)(2) of the Act[31], that the proposed rule change (File No. SR–NYSE–2003–05) be approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[32]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6073 Filed 3–12–03; 8:45 am]

**BILLING CODE 8010–01–P**

[26] 15 U.S.C. 78s(b)(2).

[27] 15 U.S.C. 78f(b)(5).

[28] In approving the proposed rule, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78g(c)(2)(B).

[30] 17 CFR 240.403(b)(2).

[31] 15 U.S.C. 78s(b)(2).

[32] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47458; File No. SR–NYSE–2002–50]**

### Self-Regulatory Organizations; Order Approving Proposed Rule Change, as Amended by Amendment No. 1 Thereto, by the New York Stock Exchange, Inc. To Adopt Amendments to Exchange Rules 450 (''Restrictions on Giving of Proxies''), 451 (''Transmission of Proxy Material''), 452 (''Giving Proxies by Member Organizations''), and 465 (''Transmission of Interim Reports and Other Material'')

March 6, 2003.

On October 16, 2002, the New York Stock Exchange, Inc. (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b-4 thereunder,[2] a proposed rule change to amend NYSE Rule 450 (''Restriction on Giving of Proxies''), NYSE Rule 451 (''Transmission of Proxy Material''), NYSE Rule 452 (''Giving Proxies by Member Organizations''), and NYSE Rule 465 (''Transmission of Interim Reports and Other Material'') to allow authorized state-registered investment advisers to receive and vote proxy materials on behalf of beneficial owners. On December 19, 2002, the NYSE amended the proposal to define the term ''state'' in proposed NYSE Rule 451 by reference to the Investment Advisers Act of 1940 (''Advisers Act''),[3] instead of the Act.[4]

The Commission published the proposed rule change, as amended, for comment in the **Federal Register** on January 28, 2003.[5] The Commission received one comment letter relating to the proposal. [6] This order approves the amended proposal.

Currently, NYSE Rules 450, 451, 452, and 465 provide beneficial owners the ability to authorize investment advisors to receive proxy material, other related issuer material and to vote proxies on their behalf, if such investment advisers are registered under the Advisers Act, exercise investment discretion pursuant to an advisory contract, and have been designated to the member organization in writing by the beneficial owner.

Title III of the National Securities Markets Improvement Act of 1996 (the ''Coordination Act'') reallocated regulatory responsibilities for investment advisers between the Commission and the states.[7] Generally, the Coordination Act provides for Commission regulation of advisers with $25 million or more of assets under management, and state regulation of advisers with less than $25 million of assets under management. As a result, the Exchange believes that the number of advisers eligible to be registered with the Commission has been reduced by approximately two-thirds. Consequently, because NYSE's current rules require the authorized investment adviser to be registered under the Advisers Act, beneficial owners cannot designate a large number of investment advisers (those with less than $25 million under management) to exercise investment discretion pursuant to an advisory contract, or to receive and vote proxy materials on their behalf. The proposed amendments would allow such authorization to be extended to advisers registered under state law.

The Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange [8] and, in particular, the requirements of section 6 of the Act.[9] The Commission finds that the proposed rule change, as amended, is consistent with section 6(b)(5) of the Act,[10] which requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade and, in general, to protect investors and the public interest. The Commission believes that amending NYSE Rules 450, 451, 452, and 465 to allow authorized state-registered advisers to receive and vote proxy materials on behalf of the beneficial owner, would allow for the reasonable expectation that all registered advisers, state and federal, subject to due authorization and regulation, be permitted to receive and vote proxy materials on their behalf. The Commission also believes that this change recognizes, and is consistent with, the regulatory scheme set up for the registration of investment advisors under state and federal law pursuant to the Coordination Act.[11]

NYSE's rules will continue to require that such investment advisers are exercising investment discretion on behalf of the beneficial owner pursuant to an advisory contract, and have been designated to the member organization in writing by the beneficial owner. These requirements should help to ensure that any state registered adviser is acting on behalf of the beneficial owner.

*It is therefore Ordered,* pursuant to section 19(b)(2) of the Act,[12] that the proposed rule change (SR–NYSE–2002–50), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6075 Filed 3–12–03; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 80b.

[4] *See* letter from Darla Stuckey, Corporate Secretary, NYSE, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated December 19, 2002 (''Amendment No. 1'').

[5] *See* Securities Exchange Act Release No. 47215 (January 17, 2003), 68 FR 4263.

[6] *See* letter from Christine A. Bruenn, NASSA President and Maine Securities Administrator, North American Securities Administrators Association, Inc. (''NASAA''), to Jonathan G. Katz, Secretary, Commission, dated February 18, 2003 (''NASAA Comment Letter''). In its comment letter, the NASAA expressed support for the proposal. *See also infra* note 11.

[7] 62 FR 28112 (May 22, 1997); Release No. IA–1633, File No. S7–31–96.

[8] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[9] 15 U.S.C. 78f.

[10] 15 U.S.C. 78f(b)(5).

[11] *See* NASAA Comment Letter, *supra* note 6. In its comment letter, the NASAA stated that while federal and state-registered advisers are distinguished based on their levels of assets under management, both federal and state-registered advisers generally perform similar functions. According to the NASAA, while not all clients may want their adviser to vote on their behalf, NASAA believes this option should be available to all investors.

[12] 15 U.S.C. 78s(b)(2).

[13] 17 CFR 200.30'3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47453; File No. SR–PCX–2003–07]**

### Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Relating to Changes in Marketing Fees Charged to Its Market Makers

March 6, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 24, 2003, the Pacific Exchange, Inc. (''PCX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

have been prepared by the PCX.[3] On February 28, 2003, PCX submitted Amendment No. 1 to the proposed rule change.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The PCX is proposing to change its marketing fee for certain options and to adopt new marketing fees for recently listed options. The text of the proposed rule change is available at the principal offices of the PCX and at the Commission.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the PCX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it had received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The PCX has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The PCX recently adopted a payment-for-order-flow program under which it charges a marketing fee ranging from $0 to $1.00 per contract on a per-issue basis.[5] The PCX segregates the funds from this fee by trading post and makes the funds available to Lead Market Makers (''LMMs'') for their use in attracting orders in the options traded at the posts. The PCX charges the marketing fees as set forth in its Schedule of Marketing Charges.

The PCX is proposing to change the marketing fee for certain options as set forth in the Schedule of Marketing Charges beginning at the commencement of the March trade month and continuing until further notice. The PCX proposes to change only the amounts of the fees that it charges for transactions in the options that are included in the proposed Schedule of Marketing Charges.[6] Any fees currently being charged for transactions in options that are not listed in this amendment to the Schedule of Marketing Charges would not be affected by the proposed rule change. The PCX believes that its proposed rule change is reasonable and equitable because it is designed to enable the PCX to compete with other markets in attracting options business.

The PCX's marketing fee program applies only to option issues classified by the PCX as a Top 250 issue. The PCX defines a Top 250 issue as one of the 250 most actively traded option issues on a national basis. For each current month, the PCX's determination of whether an equity option ranks in the top 250 most active issues will be based on volume statistics for the three calendar months of trading activity beginning four months prior to the current month.

2. Statutory Basis

The PCX believes that its proposal to amend its schedule of dues, fees and charges is consistent with Section 6(b) of the Act[7] in general, and furthers the objectives of Section 6(b)(4) of the Act[8] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among PCX members.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The PCX does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

PCX neither solicited nor received written comments concerning the proposal.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Because the foregoing rule change establishes or changes a due, fee, or other charge imposed by the PCX, it has become effective pursuant to section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f) thereunder.[10] At any time within 60 days after the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. For purposes of calculating the 60-day abrogation period, the Commission considers the proposed rule change to have been filed on February 28, 2003, the date Amendment No. 1 was filed.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing also will be available for inspection and copying at the principal office of the PCX. All submissions should refer to File No. SR–PCX–2003–07 and should be submitted by April 3, 2003.

[3] The Commission notes that in its cover letter accompanying the proposed rule change, PCX inadvertently referred to the filing as SR–PCX–2003–06.

[4] *See* letter from Mai S. Shiver, Senior Attorney, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation, Commission, dated February 28, 2003, received via facsimile on February 28, 2003. In Amendment No. 1, the PCX clarified that the marketing fee program applies only to option issues classified by the PCX as among the Top 250 issues, and described how the Top 250 issues are determined. In addition, the PCX supplemented its Schedule of Marketing Charges to include a list of 19 options issues for which the marketing fee has been reduced from $0.50 to $0.00.

[5] *See* Exchange Act Release No. 44830 (September 21, 2001), 66 FR 49728 (September 28, 2001) (SR–PCX–2001–37).

[6] The Commission notes that the PCX payment-for-order-flow program applies only to Top 250 issues. For purposes of the payment-for-order-flow-program, the PCX recalculates the Top 250 issues quarterly, based upon volume statistics for the three-month period that began four months earlier. The PCX has updated its Schedule of Marketing Charges to identify the changes to the marketing fees that the PCX is charging for the March, April, and May 2003 trading months, as part of its payment-for-order-flow program. *See* Note 4 *supra.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–5996 Filed 3–12–03; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47457; File No. SR–PCX–2003–10]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Relating to the Eligibility of Timed Orders During the Opening Auction and Market Order Auction, Amending PCXE Rules 7.34 and 7.35

March 6, 2003.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 3, 2003, the Pacific Exchange, Inc. (''PCX'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I and II, below, which the PCX has prepared. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PCX, through its wholly owned subsidiary PCX Equities, Inc. (''PCXE''), proposes to amend its rules governing the Archipelago Exchange (''ArcaEx''), the PCXE's equities trading facility, by: (1) Amending PCXE Rule 7.34(d) to clarify that a specific type of Limited Price Order; namely a Timed Order[3] designated as good from 5 a.m. (Pacific Time) or good from 6:30 a.m. (Pacific Time), will be excluded from eligibility for execution during the Opening Auction and Market Order Auction, respectively; and (2) amending PCXE Rule 7.35(a) through (c) to exclude specified Timed Orders during the applicable auctions. The text of the proposed rule change is below. New text is italicized.

**Rule 7—Equities Trading**

*Orders and Modifiers*

Trading Sessions

Rule 7.34(a)–(c)—No change.

(d) Order Permitted in Each Session.

(1) During the Opening Session:

(A)–(F)—No change.

(G) *Limited Price Orders are eligible for execution during the Opening Session; provided, however, a Timed Order designated for the Opening Session and designated as good from 5 am (Pacific Time) is not eligible for execution during the Opening Auction. Similarly, a Timed Order designated for the Opening Session and designated as good from 6:30 am (Pacific Time) is not eligible for execution during the Market Order Auction*

*(H)*—No change.

(2)–(3)—No change.

(e)–(f)—No change.

*Opening Session Auctions*

Rule 7.35(a) Order Entry and Cancellation Before Opening Auction

(1)—No change.

(2) Only Limited Priced Orders designated for the Opening Session will be eligible for the Opening Auction. *However, a Limited Price Order designated for the Opening Session and entered as a Timed Order good from 5 am (Pacific Time), is not eligible for execution during the Opening Auction.* Market orders entered before the Opening Auction or during the Opening Session will participate in the Market Order Auction. *However, a Limited Price Order designated for the Opening Session and entered as a Timed Order good from 6:30 am (Pacific Time), is not eligible for execution during the Market Order Auction.* Limited Price Orders*, including Timed Orders,* designated for the Core Trading Session and not designated for the Opening Session will become eligible for execution at the commencement of the Market Order Auction pursuant to Rule 7.35(c).

(3)–(4)—No change.

(b) Opening Auction.

(1) At 5 am (Pacific Time), Limited Priced Orders designated for the Opening Session are matched and executed in the Opening Auction*; provided, however, a Limited Price Order designated for the Opening Session and entered as a Timed Order good from 5 am (Pacific Time), is not eligible for execution during the Opening Auction.*

(2)–(3)—No change.

*(4) A Limited Price Order designated for the Opening Session and entered as a Timed Order good from 6:30 am (Pacific Time) is not eligible for execution during the Market Order Auction.*

(c)–(f)—No change.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the PCX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it had received. The text of these statements may be examined at the places specified in Item IV below. The PCX has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of those statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

ArcaEx commenced operations on March 22, 2002, replacing the PCXE's traditional trading floor facilities. As part of its continuing review of the system's functionality and its duty to ensure the reporting of current, accurate, and consistent information regarding the Indicative Price Match[4] and Imbalances[5] on ArcaEx, the PCXE proposes to amend its rule to exclude Timed Orders designated as good from 5 a.m. (Pacific Time) or 6:30 a.m. (Pacific Time) from execution during the Opening Auction and Market Order Auction, respectively.

ArcaEx operates three trading sessions each day the PCXE is open for business.[6] The proposed rule change concerns only the Opening Session. The Opening Session begins at 5 a.m. (Pacific Time) and concludes at 6:30 a.m. (Pacific Time) with the

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] CFR 240.19b–4.

[3] *See* PCXE Rule 7.31(q) (definition of a ''Timed Order'').

[4] PCXE Rule 1.1(r) provides, in part: ''[f]or purposes of the Opening Auction [and] the Market Auction, as the case may be, * * * the term ''Indicative Match Price'' shall mean for each security (1) the price at which the maximum volume of shares are executable; or (2) if there are two or more prices at which the maximum volume of shares are executable, the price that is closest to the closing price of the previous day's normal market hours * * * as determined by the Consolidated Tape will establish the opening price, provided that such price would trade through an eligible Limited Price Order designated for such an auction, then the opening price will occur at the best price level available where no trade through occurs.''

[5] PCXE Rule 1.1(q) provides, in part: ''[f]or purposes of the Opening Auction [and] the Market Auction * * * as the case may be, the term ''Imbalance'' shall mean the number of buy or sell shares that can not be matched with other shares at the Indicative Match Price at any given time.''

[6] The three trading sessions are (1) the Opening session; (2) the Core Session; and (3) the Late Trading Session. *See* PCXE Rule 7.34(a).

commencement of the Core Trading Session. The Opening Session is comprised of the Opening Auction and, thereafter, the Market Order Auction.[7] Limited Price Orders are matched in the Opening Auction or the Market Order Auction and executed at the Indicative Match Price.

ArcaEx currently permits a Timed Order designated as good from 5 a.m. (Pacific Time) and designated for the Opening Session to participate in the Opening Auction. Conversely, a Timed Order designated as good from 6:30 a.m. (Pacific Time) and designated for the Opening Session does not participate in the Market Order Auction. The proposed rule change is intended to reconcile the treatment of Timed Orders during the Opening Session. Accordingly, Timed Orders designated as good from 5 a.m. (Pacific Time) or 6:30 a.m. (Pacific Time) and designated for the Opening Session will not be eligible for inclusion in the Opening Auction or the Market Order Auction and, therefore, will not be reported for purposes of the Indicative Match Price and Imbalance. The PCX believes that the proposed change will facilitate ArcaEx's dissemination of consistent information.

2. Basis

The PCX believes that the proposed rule change is consistent with Section 6(b) of the Act[8] and furthers the objectives of Section 6(b)(5) of the Act[9] because it is designed to promote just and equitable principals of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments and perfect the mechanisms of a free and open market, and to protect investors and the public interest.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The PCX does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The PCX neither solicited nor received written comments on the proposed rule change.

[7] *See* PCXE Rule 7.35(b) and PCXE Rule 7.35(c), respectively, for a detailed discussion of the Opening Auction and Market Order Auction.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The PCX submitted a draft of this filing, including the proposed new rule text, to the Commission in fulfillment of the five-day draft notice period of Rule 19b–4(f)(6).[10] The PCX has further designated that the proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days from the date of filing, or such shorter time as the Commission may designated if consistent with the protection of investors and the public interest. Therefore, the proposed rule change has become effective immediately upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act[11] and Rule 19b–4(f)(6) thereunder.[12]

A proposed rule change filed under Rule 19b–4(f)(6)[13] does not become operative until 30 days after the date of filing or such shorter time as the Commission may designate if such action is consistent with the protection of investors and the public interest. The PCX believes that the proposed rule change will reconcile the treatment of Timed Orders during the Opening Session and will eliminate any potential confusion with respect to the use of this order modifier. The PCX also believes that the rule change is necessary and appropriate in order to promote a fair, orderly, and competitive market. Therefore, the PCX has requested that the Commission accelerate the implementation of the proposed rule changes so that it may become operative immediately, before the 30-day period specified in Rule 19b–4(f)(6)(iii).[14]

The Commission believes that it is consistent with the protection of investors and the public interest to waive the 30-day period and to designate that the proposed rule change has become operative as of March 3, 2003, the date the PCX filed the proposal with the Commission.[15] At any time within 60 days after the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

[10] 17 CFR 240.19b–4(f)(6).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6).

[13] *Id.*

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] The Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation for the sole purpose of accelerating the operative date of the proposed rule change. 15 U.S.C. 78c(f).

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. All submissions should refer to File No. SR–PCX–2003–10 and should be submitted by April 3, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 03–6069 Filed 3–12–03; 8:45 am]

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47467; File No. SR–PCX–2002–75]**

## Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Pacific Exchange, Inc., as Amended, and Notice of Filing and Order Granting Accelerated Approval to Amendment No. 2 Relating to New Order Types and To Amend PCXE Rule 7.37

March 7, 2003.

**I. Introduction**

On December 9, 2002, pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] the Pacific Exchange, Inc. (''PCX'' or ''Exchange''),

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

through its subsidiary, PCX Equities, Inc. (''PCXE''), filed with the Securities and Exchange Commission (''Commission'') a proposed rule change to establish new order types on the Archipelago Exchange (''ArcaEx''), the equity facility of the PCXE, and to amend the ArcaEx Working Order Process to enable the execution of such order types. The PCX filed Amendment No. 1 to the proposal on January 15, 2003.[3] The PCX filed Amendment No. 2 on March 7, 2003.[4] The proposed rule change, as amended by Amendment No. 1, was published for comment and appeared in the **Federal Register** on January 29, 2003.[5] The Commission received no comment letters in response to the proposed rule change. This order approves the PCX's proposed rule change, as amended, and notices and grants accelerated approval to Amendment No. 2 to the proposed rule change.

## II. Description of the Proposal

*The proposal would amend PCXE rules to:* (1) Adopt several new order types to accommodate the trading of securities listed on the Nasdaq Stock Market, Inc. (''Nasdaq''), on an unlisted trading privileges (''UTP'') basis; (2) amend PCXE Rule 7.37 to provide for a limited exemption from the ArcaEx guarantee of executions at the NBBO or better for certain order types trading Nasdaq securities; (3) reflect the operational requirements of two proposed order types in the Working Order Process; and (4) make various minor technical rule changes to conform to the Nasdaq UTP Plan, which extends UTP to Nasdaq SmallCap securities.

### *A. Proposed New Order Types*

As part of its ongoing preparation for the trading of Nasdaq securities on the ArcaEx pursuant to UTP,[6] PCX proposes to make several new order types available to Electronic Trading Permit (''ETP'') Holders[7] and Sponsored Participants[8] (collectively ''Users''), which are currently in use on the Archipelago electronic communication network (''ECN'').[9] The proposed new order types are discussed below.

#### 1. Inside Limit Order

An Inside Limit Order is a limit order that is to be executed in whole or in part on ArcaEx. If the order were not executed in its entirety, the remaining portion of the order would be routed pursuant to PCXE Rule 7.37(d) to the market participant[10] with the best displayed price. Any unfilled portion of the order would not be routed to the next best price level until all quotes at the current best bid or offer are exhausted. If the Inside Limit Order were no longer marketable, it would be ranked in the Arca Book pursuant to PCXE Rule 7.36.

#### 2. Discretionary Orders

Currently, a User can submit a Discretionary Order, which is an order to buy or sell a stated amount of a security at a specified, undisplayed price (the ''discretionary price''), as well as at a specified, displayed price. The undisplayed prices of a Discretionary Order are represented in the Working Order Process[11] and can be matched with orders on the other side of the market under prescribed conditions. The Exchange proposes to adopt two new variations of the Discretionary Order called a ''Passive Discretionary Order'' and a ''Discretion Limit Order.'' A summary of these proposed order types is discussed below.

*a. Passive Discretionary.* The Exchange proposes to add PCXE Rule 7.31(h)(2)(A) to define a Passive Discretionary Order. A Discretionary Order may be designated as a Passive Discretionary Order and such order would be routed pursuant to PCXE Rule 7.37(d) only if the displayed price is marketable against an away market participant. If the discretionary price of a Passive Discretionary Order were marketable, such order would only interact with trading interest in the ArcaEx Book pursuant to PCXE Rule 7.37(b)(2) and would not be routed away. Under the proposal, the Passive Discretionary order type will be available for exchange-listed and Nasdaq securities. For Passive Discretionary Orders in exchange-listed securities, if the discretionary price is marketable, such order will only interact with trading interest in the ArcaEx Book pursuant to PCXE Rule 7.37(b)(2) and will not be routed away. A Passive Discretionary Order for ITS Trade-Through Exempt Securities (as defined in PCXE Rule 7.37) will be permitted to trade at a price no more than three cents ($0.03) away from the NBBO displayed in the Consolidated Quote. For Passive Discretionary Orders in Nasdaq securities, if the discretionary price can be matched against orders in the ArcaEx Book, then such order will interact with trading interest in the ArcaEx Book pursuant to 7.37(b)(2). The NBBO or better execution guarantee set forth in PCXE Rule 7.37 will not apply to Passive Discretionary Orders in Nasdaq securities. Instead, Passive Discretionary Orders in Nasdaq securities would trade at no worse than the ArcaEx BBO.[12]

In the event that a Passive Discretionary Order routed from ArcaEx to another market participant is not executed in its entirety at the other market participant's quote, ArcaEx would attempt to execute the residual trading interest in the ArcaEx Book pursuant to PCXE Rule 7.37. Finally,

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[3] In Amendment No. 1, the Exchange submitted a new Form 19b–4, which replaced the original filing in its entirety.

[4] *See* Letter from Peter Bloom, Acting Managing Director, Regulatory Policy, PCX, to Marc McKayle, Special Counsel, Division of Market Regulation, Commission, dated March 7, 2003 (''Amendment No. 2''). In Amendment No. 2, the Exchange made various clarifying and technical amendments to the proposed rule text to: (1) Reference the ''Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges (''Nasdaq Unlisted Trading Privileges Plan'') in proposed PCXE Rule 1.1(aa), (2) clarify that the term ''OTC/UTP Listing Market'' shall have a meaning consistent with the Nasdaq Unlisted Trading Privileges Plan, (3) clarify the definition of ''Sweep Reserve Order'' by replacing the word ''price'' with the word ''size,'' (4) clarify the definition of ''Random Reserve Order'' by indicating that the random reserve value is expressed in round-lot increments and by correcting a grammatical error, (5) amend the definition of ''Pegged Order'' to reflect that the display price will track the relevant Consolidated Quote information for such orders on a real-time basis and that the displayed price of a Pegged Order designated as a Discretionary Order will track the National Best Bid or Offer (''NBBO''), and that the discretionary price of such order would re-price in correlation to any changes to the displayed price, and (6) clarify that Immediate or Cancel (''IOC''), NOW, Post No Preference (''PNP''), Passive Discretionary, Discretion Limit, IOC Cross and PNP Cross orders in Nasdaq securities would received executions no worse than the ArcaEx Best Bid or Offer (''BBO'').

[5] Securities Exchange Act Release No. 47223 (January 21, 2003), 68 FR 4527 (January 29, 2003) (SR–PCX–2002–75).

[6] The Nasdaq UTP Plan was initially approved in 1990. *See* Securities Exchange Act Release No. 28146 (June 26, 1990), 55 FR 27919 (July 6, 1990) (S7–24–89). It has subsequently been amended on several occasions to, among other things, admit new Participants. *See also* Securities Exchange Act Release No. 46381 (August 19, 2002), 67 FR 54687 (August 23, 2002) (S7–24–89) (Order approving most recent amendments to Nasdaq UTP Plan, the 13th Amendment).

[7] *See* PCXE Rule 1.1(n).

[8] A ''Sponsored Participant'' means ''a person which has entered into a sponsorship arrangement with a Sponsoring ETP Holder pursuant to [PCXE] Rule 7.29.'' *See* PCXE Rule 1.1(tt).

[9] The broker-dealer commonly referred to as the Archipelago ECN is Archipelago Securities, a wholly owned subsidiary of Archipelago Holdings LLC and a member of the NASD. The ECN function will cease to operate as such once all the Nasdaq securities have been transferred to ArcaEx.

[10] *See* PCXE Rule 1.1(w) (definition of ''market participant'').

[11] The Working Order Process is the third step in the ArcaEx execution algorithm. Working Orders are defined to include any order with a conditional or undisplayed price and/or size, including All-or-None, Discretionary, and Reserve Orders. *See* PCXE Rule 7.37(b)(2) (description of ''Working Order Process'').

[12] *See* Amendment No. 2, *supra* note 4.

Passive Discretionary Orders that are not marketable would be ranked in the ArcaEx Book pursuant to PCXE Rule 7.36.

*b. Discretion Limit.* The Exchange also proposes to add PCXE Rule 7.31(h)(2)(B) to define a Discretion Limit Order. A Discretionary Order may be designated as a Discretion Limit Order for Nasdaq securities only. If the discretionary price of a Discretion Limit Order could be matched against trading interest in the ArcaEx Book, then such order would be executed at the discretionary price or better against the displayed share size of available trading interest in the ArcaEx Book, regardless of size. If the discretionary price of a Discretion Limit Order could be matched against an away market participant, then such order would be routed pursuant to PCXE Rule 7.37(d) but only if the displayed share size of the Discretion Limit Order is equal to or less than the displayed share size of the away market participant. The NBBO or better execution guarantee set forth in PCXE Rule 7.37 would not apply to Discretion Limit Orders. Instead, Discretion Limit Orders, which will only be available for the trading of Nasdaq Securities, will not trade at a price inferior to the ArcaEx BBO. [13]

3. Reserve Orders

Under current PCXE Rule 7.31(h)(3), a Reserve Order is a limit order with a portion of the size displayed and with a reserve portion of the size (''reserve size'') that is not displayed on the ArcaEx Book. With this filing, the Exchange proposes to adopt two new variations of the Reserve Order, a ''Sweep Reserve Order'' and a ''Random Reserve Order.'' These proposed order types would be ranked and maintained in the Display Order Process [14] and/or Working Order Process of the ArcaEx Book according to price-time priority and would be processed for internal matches in the same manner as standard Reserve Orders pursuant to PCXE Rule 7.37(b)(2). The proposed rule change regarding Sweep Reserve Orders should clarify how ArcaEx treats such orders when routing to other market participants is required. In the case of a Random Reserve Order, the proposed rule change would allow a User to define the original display quantity and a random reserve value in a share amount that would be used to determine the displayed quantity within a defined range each time it is replenished. These proposed order types are discussed separately below.

a. *Sweep Reserve Order.* Under proposed PCXE Rule 7.31(h)(3)(A), a Reserve Order may be designated as a Sweep Reserve Order. Based upon a User's instruction, if the displayed price of a Sweep Reserve Order is marketable against an away market participant(s), then such order will be routed (i) serially as component orders, such that each component corresponds to the displayed size, or (ii) only once in its entirety, including both the displayed and reserve portions. The Exchange believes that this rule change codifies current order routing methodology, and believes that the proposed Sweep Reserve Order type is clearly implied in current PCXE Rule 7.37(d)(2)(A)(ii).

b. *Random Reserve Order.* The Exchange proposes to add PCXE Rule 7.31(h)(3)(B) to define a Random Reserve Order. Under the rule proposal, a User could determine a display and reserve quantity for a Reserve Order. In addition, a User could also define a random reserve delta (expressed in a share amount) to determine the number of shares to display when the quote is refreshed from reserve.[15] Users are required to display at least 100 shares for all Reserve Orders including Random Reserve Orders. If the User does not specify the random reserve delta or the random reserve delta is set to zero, the ArcaEx system would assign the displayed size of the Reserve Order to vary to within 20% of the original specified displayed size. Should a User enter a Random Reserve Order with a display amount of 500 shares or less and a random reserve delta that is unspecified or set to zero, the order would be handled as a regular Reserve Order. The ArcaEx system would refresh the display quantity to the original displayed size, and would not vary the display quantity.

4. Pegged Orders

The Exchange proposes to modify the ArcaEx trading system to accept Pegged Orders. A Pegged Order is a limit order to buy or sell a stated amount of a security at a display price set to track the current bid or ask of the NBBO in an amount specified by the User.[16] The tracking of the relevant Consolidated Quote information for Pegged Orders would occur dynamically on a real-time basis. The associated price of each Pegged Order that is updated would be assigned a new entry time with priority in accordance with PCXE Rule 7.36(a). A Pegged Order may be designated as a Reserve Order or Discretionary Order and would be subject to the applicable order execution rules. The displayed price of a Pegged Order designated as a Discretionary Order would track the NBBO, and discretionary price of such order would re-price in correlation to any changes to the displayed price.[17] Finally, Pegged Orders are only eligible during the Core Session.

*B. Changes to PCXE Rule 7.37*

The Exchange's current rules governing the order execution processes for orders in the ArcaEx Book are set forth in PCXE Rule 7.37. Presently, PCXE Rule 7.37 provides, in part, that for an execution to occur in any Order Process, the price must be equal to or better than the NBBO. The requirements of this rule do not apply to orders designated as IOC, NOW and PNP in certain exchange-traded funds (''ETFs'') that are subject to the Commission's order granting a *de minimis* exemption from the trade-through restrictions of the Intermarket Trading System (''ITS'') Plan; provided, however, that any resulting executions will be at a price no more than three cents ($0.03) away from the NBBO displayed in the Consolidated Quote.[18] The Exchange proposes that the requirements of PCXE Rule 7.37 would not apply to existing order types (IOC, NOW and PNP orders) and proposed new order types (Passive Discretionary, Discretion Limit, IOC Cross and PNP Cross)[19] in Nasdaq securities, provided however that such orders in Nasdaq securities would not result in an execution at a price less than the ArcaEx BBO.[20]

*C. Working Order Process*

The Exchange proposes the following conforming changes to certain provisions of the Working Order Process set forth in PCXE Rule 7.37(b)(2):

Under the proposal PCXE Rule 7.37(b)(2) will be amended to clarify the

[13] *See* Amendment No. 2, *supra* note 4.

[14] The Display Order Process is the second step in the ArcaEx execution algorithm. In this process, the ArcaEx system matches an incoming marketable order against orders in the Display Order Process at the display price of the resident order for the total size available at the that price or for the size of the incoming order. *See* PCXE Rule 7.37(b)(1) description of ''Display Order Process'').

[15] *See* Amendment No. 2, supra note 4.

[16] *See* proposed PCXE Rule 7.31(cc) (definition of ''Pegged Order'').

[17] *See* Amendment No. 2, *supra* note 4.

[18] See Securities Exchange Act Release No. 46428 (August 28, 2002), 67 FR 56607 (September 4, 2002) (Order Pursuant to Section 11A of the Act and Rule 11Aa3–2(f) thereunder Granting a De Minimis Exemption for Transactions in Certain ETFs from the ITS Trade-Through Provisions. *See* also Securities Exchange Act Release No. 46684 (October 17, 2002), 67 FR 65618 (October 25, 2002) (SR–PCX–2002–69).

[19] *See* Securities Exchange Act Release No. 47178 (January 13, 2003), 68 FR 3076 (January 22, 2003) (Order approving File No. SR–PCX–2002–74). The Commission recently approved a separate proposed rule change establishing IOC Cross and PNP Cross Orders.

[20] *See* Amendment No. 2, *supra* note 4.

conditions in which a Passive Discretionary Order and Discretion Limit Order would be routed to an away market participant's quote. Passive Discretionary Orders would be routed away only if the displayed price is marketable against an away market participant. Discretion Limit Orders would be routed away only if the displayed share size of such order is equal to or less than the displayed share size of the away market participant.

Several pricing scenarios have been added to the Working Order Process regarding incoming marketable orders that could be matched against a Passive Discretionary Order. First, for Nasdaq securities, if the ArcaEx BBO is outside the NBBO and a Passive Discretionary Order(s) within the Working Order Process has a discretionary price worse than the NBBO, then the incoming order would execute against such Passive Discretionary Order(s) at the price of the incoming order or the displayed price of the Discretionary Order(s), whichever is better. Second, for Nasdaq securities, if the ArcaEx BBO is outside the NBBO and a Passive Discretionary Order(s) within the Working Order Process has a discretionary price equal to or better than the NBBO, then the incoming order would execute against such Passive Discretionary Order(s) pursuant to current PCXE Rule 7.37(b)(2)(A)(ii). Finally, for ITS Trade-Through Exempt Securities (as defined in PCXE Rule 7.37), if the ArcaEx BBO is outside the NBBO and a Passive Discretionary Order(s) within the Working Order Process has a discretionary price worse than the NBBO by three cents ($0.03) or less, the incoming order would execute against such Passive Discretionary Order(s) at the price of the incoming order or the displayed price of the Discretionary Orders(s), whichever is better.

*D. Technical Changes*

The Exchange has proposed to adopt several minor technical changes throughout PCXE Rules 1.1 and 7.18 to conform to the Nasdaq UTP Plan, which extends UTP to Nasdaq SmallCap securities. Accordingly, the Exchange is proposing to delete references to the term ''Nasdaq/NM Security'' and replacing it with ''Nasdaq Security.'' In addition, several definitions contained in PCXE Rule 1.1 are being amended to reflect the change in name of the Nasdaq UTP Plan. Finally, current PCXE Rule 1.1(jj), which defines the term ''OTC/UTP Primary Market,'' is being amended to reflect that the Listing Market, rather than the Primary Market, would have the authority to call a Regulatory Halt pursuant to PCXE Rule 7.18(c). A definition of ''OTC/UTP Listing Market'' is being adopted from the Nasdaq UTP Plan.[21]

**III. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning Amendment No. 2, including whether Amendment No. 2 is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. All submissions should refer to Amendment No. 2 of File No. SR–PCX–2002–75 and should be submitted by April 3, 2003.

**IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change**

After careful review, the Commission finds, for the reasons discussed below, that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the PCX.[22] The Commission finds that the proposed rule change is consistent requirements of section 6(b)(5) of the Act[23] and the objectives of section 11A(a)(2) of the Act.[24] Section 6(b)(5) requires, among other things, that the rules of a national securities exchange be designed to facilitate transactions in securities and to remove impediments to and perfect the mechanism of a free and open market and a national market system. Section 11A(a)(2) of the Act authorizes the Commission to establish a national market system for securities, which should include the establishment of new data processing and communications techniques.[25]

In proposing to establish new order types on ArcaEx, PCX seeks to provide market participants with more choices that will permit a more accurate representation of their trading interest on its electronic auction trading facility. In the Commission's view, the proposed order types could provide a new and advanced way for sophisticated trading interests and strategies to be represented and executed on ArcaEx. Further, the Commission believes that by amending the rules to include pricing and execution scenarios for the new order types in the Working Order Process the proposed rule change should assist Users in effectuating such trading interests and strategies. The Commission believes that the implementation of the new order types may enhance the ability of investors to represent their trading interest more completely than is currently possible on ArcaEx. In addition, the new order types may facilitate enhanced order interaction and foster price competition. The depth and liquidity of the market on ArcaEx could increase as a result of the enhanced interest and competition on ArcaEx. The Commission believes that, such order types could assist ArcaEx in attracting new market participants and to increase order flow to the PCXE, which in turn could promote greater competition among market centers.

Pursuant to PCXE Rule 7.37 quotes and orders on the ArcaEx, except those in ITS Trade-Through Exempt Securities, must be executed at a price equal to or better than the NBBO, unless ArcaEx has routed the order to an away market at the NBBO. Under the proposal, executions in IOC, NOW, PNP, Passive Discretionary, Discretion Limit, IOC Cross, and PNP Cross orders for Nasdaq securities would also be included in the ArcaEx exception to the PCXE Rule 7.37 price protection provision. Specifically, executions in such orders in Nasdaq securities could be effected at a price no worse than the ArcaEx BBO. The Commission notes that currently there is no trade-through prohibition for Nasdaq securities because the Nasdaq UTP Plan does not provide for intermarket linkages between its participants like the listed securities market.[26] The Commission believes that without the presence of an intermarket linkage for Nasdaq UTP Plan participants it would be impracticable for PCXE to attempt to provide intermarket price protection for the above-mentioned orders in Nasdaq securities. Nonetheless, the Commission emphasizes that this approval order does not diminish investor protections, and that such orders in Nasdaq

[21] *See supra* note 6.

[22] In approving this rule, the Commission notes that it has considered the proposal's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[23] 15 U.S.C. 78f(b)(5).

[24] 15 U.S.C. 78k–1(a)(2).

[25] 15 U.S.C. 78k–1(a)(2).

[26] *See supra* note 6.

securities on ArcaEx are still subject to a broker's duty of best execution for its customer.

The Commission finds good cause for approving Amendment No. 2 to the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register.** In Amendment No. 2, the Exchange made various clarifying and technical amendments to the proposed rule text to: (1) Reference the ''Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges'' in proposed PCXE Rule 1.1(aa), (2) clarify that the term ''OTC/UTP Listing Market'' shall have a meaning consistent with the Nasdaq Unlisted Trading Privileges Plan, (3) clarify the definition of ''Sweep Reserve Order'' by replacing the word ''price'' with the word ''size,'' (4) clarify the definition of ''Random Reserve Order'' by indicating that the random reserve value is expressed in share amounts and by correcting a grammatical error, (5) amend the definition of ''Pegged Order'' to reflect that the display price will track the relevant Consolidated Quote information for such orders on a real-time basis and that the displayed price of a Pegged Order designated as a Discretionary Order will track the NBBO, and that the discretionary price of such order would re-price in correlation to any change in the displayed price, and (6) clarify that IOC, NOW, PNP, Passive Discretionary, Discretion Limit, IOC Cross and PNP Cross orders in Nasdaq securities will received executions at a price no worse than the ArcaEx BBO. Because Amendment No. 2 is of a technical, clarifying, non-substantive nature, and does not raise any novel regulatory issues or issues that were not considered by the Commission prior to its submission, the Commission finds good cause for accelerating approval of the proposed rule change, as amended by Amendment No. 2.

## V. Conclusion

*It is therefore ordered,* pursuant to section 19(b)(2) of the Act,[27] that the proposed rule change, (File No. SR–PCX–2002–75) as amended, be, and it hereby is approved.

[27] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[28]

**Margaret H. McFarland,**

*Deputy Secretary.*

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## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–47456; File No. SR–Phlx–2002–77]**

## Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 Thereto by the Philadelphia Stock Exchange, Inc. To Adopt a Specialist Revenue Sharing Plan for Trades in the Nasdaq-100 Index Tracking Stock

March 6, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 16, 2002, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission''), the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Phlx. The Exchange amended the proposal on February 28, 2003.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx proposes to amend its schedule of dues, fees and charges to adopt a Specialist Revenue Sharing Plan for trades in the Nasdaq-100 Index Tracking Stock (''QQQ'').SM [4] Under this program, the Exchange is proposing to share with the QQQ specialist unit a portion of the revenues that the Exchange receives under the Consolidated Tape Association (''CTA'') Plan [5] attributable to the QQQ (which is reportable on Tape B).[6] The Exchange proposes to begin its program on November 1, 2002.

The text of the proposed rule change is set forth below. Additions are in italics.

*Specialist Revenue Sharing Program for Nasdaq-100 Index Tracking Stock (''QQQ'')*

*The Exchange will share a portion of net revenues that it receives for Tape B under the Consolidated Tape Association (''CTA'') Plan attributable to the Nasdaq-100 Index Trading Stock (''QQQ'') with the specialist unit for the QQQ. The Specialist Revenue Sharing Program operates as follows:*

- *Revenues under the CTA Plan are distributed to Plan Participants on a quarterly basis. Each quarter, the Phlx will start its calculation with the quarterly revenues actually received for Tape B.*
- *First, Phlx will determine the portion of such quarterly revenues attributable to the trading of QQQ for each calendar month in the quarter to which the revenue is attributed.*
- *Then, Phlx will subtract the amount it owes Nasdaq under its license agreement for each such calendar month, to arrive at the ''Monthly Residual QQQ Tape Revenue'' for that month.*
- *The Monthly Residual QQQ Tape Revenue will be shared between Phlx and the QQQ specialist unit in the following order of priority, in each case to the extent that Monthly Residual QQQ Tape Revenues are available:*

(i) *Phlx will receive the first $15,000 per month of the Monthly Residual QQQ Tape Revenue to cover, at a minimum, its estimated monthly costs for operating and regulating trading of the QQQ on the Exchange;*

(ii) *the specialist unit will receive the next $15,000 per month; and*

[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On February 28, 2003, the Exchange filed a Form 19b–4, which replaced the original filing in its entirety (''Amendment No. 1''). In Amendment No. 1, the Exchange made technical corrections to the proposed rule text.

[4] The Nasdaq-100®, Nasdaq-100 Index®, Nasdaq®, The Nasdaq Stock Market®, Nasdaq-100 Shares SM, Nasdaq-100 Trust SM, Nasdaq-100 Index Tracking Stock SM, and QQQ SM are trademarks or service marks of The Nasdaq Stock Market, Inc. (''Nasdaq'') and have been licensed for use for certain purposes by the Phlx pursuant to a License Agreement with Nasdaq. The Nasdaq-100 Index® (the ''Index'') is determined, composed, and calculated by Nasdaq without regard to the Licensee, the Nasdaq-100 Trust SM, or the beneficial owners of Nasdaq-100 Shares SM. Nasdaq has complete control and sole discretion in determining, comprising, or calculating the Index or in modifying in any way its method for determining, comprising, or calculating the Index in the future.

[5] The CTA Plan is a national market system plan approved by the Commission pursuant to section 11A of the Act, (15 U.S.C. 78k–1, and Rule 11Aa3–2 thereunder, 17 CFR 240.11Aa3–2); CTA Plan: Second Restatement of Plan Submitted to the Securities and Exchange Commission Pursuant to Rule 11Aa3–1 under the Act, May 1974 as restated March 1980 and December 1995. The CTA Plan governs, among other things, the collection, consolidation and dissemination of transaction reports in certain securities and the distribution of the revenues derived therefrom among parties to the CTA Plan, which are known as the Plan Participants.

[6] This proposal applies only to QQQ and to no other Tape B security nor any Tape A security.

(iii) *Phlx and the specialist unit will share equally, subject to reasonable rounding, any remaining Monthly Residual QQQ Tape Revenue for that month.*

*Phlx intends to perform this calculation monthly and then make distributions to the specialist unit quarterly, after it receives its Tape B distribution under the Plan for that quarter and following a reasonable processing period of ten business days.*[I]

*The program will apply to Tape B revenues in respect of QQQ trading on or after November 1, 2002.*[II]

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Phlx has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

### *A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The purpose of the proposed rule change is to attract additional business in the QQQ equity product through a Specialist Revenue Sharing Program. The Specialist Revenue Sharing Program is intended to provide the specialist unit with incentives to grow its specialist activity in the QQQ by reducing its costs of doing business and providing it with additional funds to commit to trading to promote liquidity.

The Specialist Revenue Sharing Program would operate as follows: Revenues under the CTA Plan are distributed to Plan Participants on a quarterly basis. Each quarter, the Phlx would start its calculation with the quarterly revenues actually received for Tape B in respect of a given, prior quarter; such quarterly revenues are usually received 45 days after the end of a quarter. First, the Phlx would determine the portion of such quarterly revenues attributable to trading in the QQQ for each calendar month in that quarter.[7] Then, the Phlx would subtract the amount it owes Nasdaq under its license agreement. The remainder (if any) respecting that calendar month (''Monthly Residual QQQ Tape Revenue'') would be shared between the Phlx and the QQQ specialist unit in the following order of priority, in each case to the extent that Monthly Residual QQQ Tape Revenues are available: (i) The Phlx would receive the first $15,000 per month of the Monthly Residual QQQ Tape Revenue to cover, at a minimum, its estimated costs for operating and regulating trading of the QQQ;[8] (ii) the specialist unit would receive the next $15,000 per month; and (iii) the Phlx and the specialist unit would share equally, subject to reasonable rounding, any remaining Monthly Residual QQQ Tape Revenue for that month. The proposal would be applied separately to each month; trades from one month may not be transferred to or aggregated with trades from another month.

The Phlx intends to perform this calculation in respect of each monthly period and then make distributions to the specialist unit quarterly, after it receives its Tape B distribution under the Plan and following a reasonable processing period of ten business days.[9] The program would apply to revenue in respect of QQQ trading on and after November 1, 2002.

2. Statutory Basis

The Phlx believes that the proposed rule change is consistent with the Act, including section 6(b)[10] and section 11A of the Act,[11] and will further the objectives of section 6(b)(5) of the Act[12] by promoting just and equitable principles of trade, removing impediments to and perfecting the mechanism of a free and open market and a national market system and, in general, protecting investors and the public interest, by encouraging use of the Phlx for trading the QQQ. Similarly, the Phlx believes that the Specialist Revenue Sharing Program for QQQ is consistent with section 11A of the Act,[13] because it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure: (i) Economically efficient execution of securities transactions; and (ii) fair competition among exchange markets and between exchange markets and markets other than exchange markets. It also furthers the objectives of section 6(b)(4) of the Act[14] in that it is an equitable allocation of reasonable dues, fees, and other charges among Exchange members.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Phlx does not believe that the proposed rule change will impose any inappropriate burden on competition. The Phlx states that the proposal is designed to attract additional business to the Exchange in the QQQ by reducing the specialist unit's costs and providing it with additional funds to commit to trading, and, thus, should promote competition among market centers trading such securities.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Phlx has neither solicited nor received written comments with respect to the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Phlx consents, the Commission will:

(A) By order approve such proposed rule change, or,

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

## IV. Solicitation of Comments

On July 2, 2002, the Commission issued an Order abrogating certain proposed rule changes relating to market data revenue sharing

[I] *Accordingly, this proposal is dependent upon the Exchange actually collecting its quarterly distribution of Tape B revenues. Any transaction or other fees that the QQQ specialist unit may owe to the Exchange are handled separately from this program, pursuant to the Exchange's fee schedules and billing practices.*

[II] *For the first quarter of implementation, because the program will begin on November 1, 2002, the calculations will be based on the quarterly revenues received for the period November 1–December 31, 2002 (excluding the month of October).*

[7] The Phlx states that its total revenue Tape B distribution may be attributable to trades in securities other than QQQ.

[8] The Exchange will periodically reconsider whether this amount is appropriate, and may adjust this figure from time to time, pursuant to a proposed rule change.

[9] *Accordingly, this proposal is dependent upon the Exchange actually collecting its quarterly distribution of Tape B revenues. Any transaction or other fees that the QQQ specialist unit may owe to the Exchange are handled separately from this program, pursuant to the Exchange's fee schedules and billing practices.*

[10] 15 U.S.C. 78f.

[11] 5 U.S.C. 78k–1.

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78k–1.

[14] 15 U.S.C. 78f(b)(4).

programs.[15] In that Order, the Commission expressed concern that the subject proposed rule changes raised ''serious questions as to whether they are consistent with the Act and with the protection of investors.'' Specifically, the Commission questioned the effect of market data rebates on the accuracy of market data, and on the regulatory functions of self-regulatory organizations.

The Commission now solicits comment on the Phlx proposed rule change, and in general, on (1) Market data fees; (2) the collection of market data fees; (3) the distribution of market data rebates; (4) the effect of market data revenue sharing programs on the accuracy of market data; and (5) the impact of market data revenue sharing programs on the regulatory functions of self-regulatory organizations.

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR–Phlx–2002–77 and should be submitted by April 3, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

**Margaret H. McFarland.**

*Deputy Secretary.*

[FR Doc. 03–6076 Filed 3–12–03; 8:45 am]

**BILLING CODE 8010–01–P**

[15] *See* Securities Exchange Act Release No. 46159 (July 2, 2002), 67 FR 45775 (July 10, 2002) (File Nos. SR–NASD–2002–61, SR–NASD–2002–68, SR–CSE–2002–06, and SR–PCX–2002–37) (Order of Summary Abrogation).

[16] 17 CFR 200.30–3(a)(12).

## DEPARTMENT OF STATE

**[Public Notice 4299]**

## Bureau of Educational and Cultural Affairs Request for Grant Proposals: Central and Eastern European Professional Exchanges and Training Program for Albania, Bosnia-Herzegovina, Bulgaria, Croatia, Estonia, Kosovo, Latvia, Lithuania, Macedonia, Romania, and Serbia and Montenegro

**SUMMARY:** The Europe/Eurasia division of the Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs announces an open competition for Central and Eastern European Professional Exchanges and Training Programs for Albania, Bosnia-Herzegovina, Bulgaria, Croatia, Estonia, Kosovo, Latvia, Lithuania, Macedonia, Romania, and Serbia and Montenegro. Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3) may submit proposals that support international projects in the United States and overseas involving current or potential leaders.

Interested applicants should read the complete **Federal Register** announcement before addressing inquiries to the Office of Citizen Exchanges or submitting proposals.

*Announcement Title and Number:* All correspondence with the Bureau concerning this RFGP should reference the above title and number ECA/PE/C/EUR–03–39.

**FOR FURTHER INFORMATION CONTACT:** The Office of Citizen Exchanges, ECA/PE/C/EUR, Room 224, U.S. Department of State, SA–44, 301 4th Street, SW., Washington, DC 20547, Attention: Central and Eastern Europe Professional Exchanges and Training Program, telephone number: 202–205–3003, fax number 202–619–4350 or *kturner@pd.state.gov* to request a Solicitation Package. The Solicitation Package contains detailed award criteria, required application forms, specific budget instructions, and standard guidelines for proposal preparation.

For specific inquiries, please contact Bureau program officers by phone or e-mail: Kendra Davis (202) 619–5328 (*kldavis@pd.state.gov*); Michael George (202) 619–5330 (*mdgeorge@pd.state.gov*); Brent Beemer (202) 401–6887 (*bbeemer@pd.state.gov*); or Henry Scott (202) 619–5327 (*hscott@pd.state.gov*).

Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

### To Download a Solicitation Package via Internet

The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/education/RFGPs*. Please read all information before downloading.

### General Program Guidelines

Applicants should identify the local organizations and individuals in the counterpart country with whom they are proposing to collaborate and describe in detail previous cooperative programming and/or contacts. Specific information about the counterpart organizations' activities and accomplishments should be included in the section on Institutional Capacity. Proposals should contain letters of support tailored to the project being proposed from foreign-country partner organizations.

Exchanges and training programs supported by institutional grants from the Bureau should operate at two levels: they should enhance institutional partnerships, and they should offer practical information and experience to individuals and groups to assist them with their professional responsibilities. Strong proposals usually have the following characteristics:

- A proven track record of working in the proposed issue area and country;
- Experienced staff with language facility and a commitment by the staff to monitor projects locally to ensure implementation;
- A clear, convincing plan showing how permanent results will be accomplished as a result of the activity funded by the grant; and
- A follow-on plan that includes activities beyond the conclusion and scope of the Bureau grant.

Proposal narratives should clearly demonstrate an organization's commitment to consult closely with the Public Affairs Section, and when required, other officers at the U.S. Embassy. Proposal narratives must confirm that all materials developed for the project will acknowledge Bureau funding for the program as well as a commitment to invite representatives of the Embassy and/or Consulate to participate in various program sessions/site visits. Please note that this will be a formal requirement in all final grant awards.

Organizations with less than four years of experience managing

international exchange programs are limited to requesting $60,000 in funds.

**Suggested Program Designs**

Bureau-supported exchanges may include internships; study tours; short-term, non-technical experiential learning, extended and intensive workshops and seminars taking place in the United States or overseas. Examples of program activities include:

1. A U.S.-based program that includes: Orientation to program purposes and to U.S. society; study tour/site visits; professional internships/placements; interaction and dialogue; hands-on training; professional development; and action plan development. Proposals that include U.S.-based training will receive the highest priority.

2. Capacity-building/training-of-trainer (TOT) workshops to help participants to identify priorities, create work plans, strengthen professional and volunteer skills, share their experience with committed people within each country, and become active in a practical and valuable way.

3. Site visits by U.S. facilitators/experts to monitor projects in the region and to provide additional training and consultations as needed.

*Activities ineligible for support:* The Office does not support proposals limited to conferences or seminars (*i.e.*, one to fourteen-day programs with plenary sessions, main speakers, panels, and a passive audience). It will support conferences only when they are a small part of a larger project in duration that is receiving Bureau funding from this competition. The Office will only support workshops, seminars and training sessions that are an integral part of a larger project. No funding is available exclusively to send U.S. citizens to conferences or conference-type seminars overseas; nor is funding available for bringing foreign nationals to conferences or to routine professional association meetings in the United States.

**Selection of Participants**

All grant proposals should clearly describe the type of persons who will participate in the program as well as the participant selection process. For programs that include U.S. internships, applicants should submit letters of support from host institutions. In the selection of foreign participants, the Bureau and U.S. Embassies will review all participant nominations and may accept or refuse participants recommended by grantee institutions. When American participants are selected, grantee institutions must provide their names and brief biographical data to the Office of Citizen Exchanges. Priority in two-way exchange proposals will be given to foreign participants who have not previously traveled to the United States. (See section below on requirements for maintenance of and provision to the Bureau of data on participants and program activities.)

**Evaluation**

In general, evaluation should occur throughout the project. The evaluation should incorporate an assessment of the program from a variety of perspectives. Specifically, project assessment efforts will focus on: (a) Determining if objectives are being met or have been met, (b) identifying any unmet needs, and (c) assessing if the project has effectively identified resources, advocates, and financial support for the sustainability of future projects. Informal evaluation through discussions and other sources of feedback will be carried out throughout the duration of the project.

Formal evaluation must be conducted at the end of each component, should measure the impact of the activities and should obtain participants' feedback on the program content and administration. A detailed evaluation will be conducted at the conclusion of the project and a report will be submitted to the Department of State Bureau of Educational and Cultural Affairs. When possible, the evaluation should be conducted by an independent evaluator.

*Program Data Requirements:* Organizations awarded grants will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau as required. As a minimum, the data must include the following:

(1) Name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the grant or who benefit from the grant funding but do not travel.

(2) Itineraries of international and domestic travel, providing dates of travel and cities in which any exchange experiences take place. Final schedules for in-country and U.S. activities must be received by the ECA/PE/C/EUR Program Officer at least three work days prior to the official opening of the activity.

**Adherence to All Regulations Governing the J Visa**

The Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs is the official program sponsor of the exchange program covered by this RFGP, and an employee of the Bureau will be the ''Responsible Officer'' for the program under the terms of 22 CFR 62, which covers the administration of the Exchange Visitor Program (J visa program). Under the terms of 22 CFR 62, organizations receiving grants under this RFGP will be third parties ''cooperating with or assisting the sponsor in the conduct of the sponsor's program.'' The actions of grantee program organizations shall be ''imputed to the sponsor in evaluating the sponsor's compliance with'' 22 CFR 62. Therefore, the Bureau expects that any organization receiving a grant under this competition will render all assistance necessary to enable the Bureau to fully comply with 22 CFR part 62 *et seq.* The Bureau of Educational and Cultural Affairs places great emphasis on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by grantee program organizations and program participants to all regulations governing the J visa program status. Therefore, proposals should explicitly state in writing that the applicant is prepared to assist the Bureau in meeting all requirements governing the administration of Exchange Visitor Programs as set forth in 22 CFR 62. If the applicant has experience as a designated Exchange Visitor Program Sponsor, the applicant should discuss their record of compliance with 22 CFR 62 *et seq.,* including the oversight of their Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements.

The Office of Citizen Exchanges of ECA will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from: United States Department of State, Office of Exchange Coordination and Designation, ECA/EC/ECD—SA–44, Room 734, 301 4th Street, SW., Washington, DC 20547, Telephone: (202) 401–9810, FAX: (202) 401–9809.

**Program Information**

*Overview*

The Bureau welcomes proposals that respond directly to the themes and countries listed below. Given budgetary considerations, projects in countries and

for themes other than those listed will not be eligible for consideration and will be ruled technically ineligible. No guarantee is made or implied that grants will be awarded in all categories.

For this competition, both single country and multi-country projects are eligible for support. In order to prevent duplication of effort, proposals should reflect an understanding of the work of international agencies so that projects complement—not duplicate—other assistance programs.

Two-way exchanges will be given the highest priority. Applicants should carefully review the following recommendations for proposals in Central and Eastern European countries.

To be eligible for a grant award under this competition, the proposed professional training and exchange projects must address one of the following specific themes, which are listed below in two categories—Country Specific Programs and Regional Programs.

*Country Specific*

Library Exchange (Bulgaria only).

Judicial Reform Project (Macedonia only).

Mayors and Local Leaders Exchange (Kosovo only).

*Regional Programs*

Media Training (Regional Program for Albania and Bosnia-Herzegovina and Bulgaria and Croatia and Macedonia and Serbia and Montenegro).

Prevention of Trafficking in Persons (Regional Program for Albania and Bosnia-Herzegovina and Bulgaria and Croatia and Kosovo and Macedonia and Romania and Serbia and Montenegro).

Anti-corruption and Ethics (Regional program for Latvia and Lithuania and Estonia).

*Country Specific (Single Country Projects Only)*

Library Exchange

Bulgaria—Single country project only.—ECA is interested in proposals that will enhance institutional relationships between U.S. and Bulgarian libraries. Projects should focus on the practical use of new technologies and the provision of library services for citizens. The exchange should examine the operation of resource centers/small libraries, including strategic planning, traditional and electronic collection development, cooperative management of information resources, public-oriented services, outreach, and marketing techniques. The Union of Librarians and Information Services Officers (the Bulgarian library association) should serve as the in-country partner organization and should assist in the recruitment and selection of participants as well as provide logistical support for any in-country activities. Activities may include training-of-trainers sessions, in-country workshops, initiatives to create professional networks or professional associations, and communication through the Internet or regularly published newsletters. Projects should also take into account the need for ongoing sharing of information, training, and concrete plans for sustainability.

Project funding: The total funding available for the Bulgaria library exchanges is approximately $200,000. The Bureau anticipates awarding one grant under this theme.

Judicial Reform

Macedonia—Single country projects only.—Judicial reform has become increasingly important in Macedonia as the government, legal professionals, and concerned citizens recognize the need for a modern, efficient court system to keep pace with the social, economic, and political changes in their country. Legal experts note that courts in Macedonia are overburdened, inefficient, and unresponsive to citizens.

This program should focus on judges and prosecutors in the Macedonian legal system. The primary aim of the program will be to establish a series of trainings, seminars and on-the-job programs in Macedonia. These programs should aim to strengthen the functions of prosecutors and judges; encourage continual reform of practices; and solidify ethical standards. ECA envisions a mix of U.S.-based trainers and Macedonian-based staff coordinating the program. Another important component of the program will be the inclusion of an established Macedonian partner organization. The hope would be that the Macedonian organization would develop its own programming and could continue to work with judges and prosecutors on its own after the grant program. A U.S. based train-the-trainers component could be included for this purpose. Coordination with the Public Affairs Section of the U.S. Embassy in Skopje during the program is essential.

Project funding: The total funding available for the Macedonia judicial reform project is approximately $200,000. The Bureau anticipates awarding one grant under this theme.

Mayors and Local Leaders Exchange

Kosovo—Single country projects only.—ECA is seeking proposals to conduct an exchange program for mayors and local leaders from Kosovo. This project will support the development of the local government sector and should be designed to offer practical, hands-on experiences for the participants. Topics to be addressed during the project should include financial management, the implementation of national policies at the local level, economic development, infrastructure support and strategic planning.

The project should consist of the following elements:

- The recruitment and selection of approximately ten participants from Kosovo;
- A U.S. component that would include a three- to five-day program in Washington, DC, where participants would be introduced to the U.S. system of government and meet with elected officials and representatives of local and regional government associations and a two- to three-week program in small- to medium-sized U.S. cities.
- In-country workshops and/or consultations that reach out to a wider audience and provide substantive follow-up to the U.S.-based visits.
- Materials development.

Participants should include both elected leaders and civil servants working at the local level. Organizations should demonstrate their ability to recruit and select candidates for participation in the program and describe how these activities will be carried out. Applicants should also identify an in-country partner institution or institutions. The partner(s) should be responsible for assisting in the recruitment and selection of participants and for providing logistical support for any in-country activities.

The proposal submitted by your organization must demonstrate how these activities/objectives will be met. Your proposal narrative should also provide detailed information on major program activities to be undertaken. Applicants should have an understanding of the current situation of Kosovo, and be willing to cooperate with Kosovo-based international organizations as well as the U.S. Office in Pristina.

This office is interested in proposals that enhance institutional relationships and offer practical information to individuals to assist them with their professional responsibilities. The projects should also take into account the need for ongoing sharing of

information, training and concrete plans for self-sustainability. Examples include: A ''train the trainers'' model (a program that includes practice presentation sessions, followed by activities coordinated and implemented by the participants in Kosovo); support for in-country training/resource centers; plans to create professional networks or professional associations; regularly published newsletters; and ongoing Internet communication.

*Project funding:* The total funding available for the Kosovo mayors and local leaders project is approximately $200,000. The Bureau anticipates awarding one grant under this theme.

*Regional Programs*

Media Training

Albania, Bosnia-Herzegovina, Bulgaria, Croatia, Macedonia, Serbia and Montenegro—Multi-country projects for all six countries only.—The Bureau is looking for proposals that will provide training for journalists, editors and media managers. The program should include an orientation session lasting approximately four days; an internship assignment of approximately five weeks in a small- to medium-sized media organization; and a two- to three-day debriefing. Projects should include both English-speaking and non-English-speaking participants; proposals should clearly describe what provisions would be made for non-English speakers. ECA will consider proposals to shorten the internships assignment in order to accommodate interpreting services for non-English speakers. ECA strongly encourages the use of locally hired interpreters. Those applicants that opt to find their own interpreters should submit a budget reflecting those costs and should demonstrate in their proposal narrative the ability to competently address interpreting requirements.

Proposals should outline hands-on, practical internships for the participants. A list of media establishments willing to host the participants as well as tentative letters of commitment should be included in the proposal. A sample program schedule or outline of a similar program that the organization has conducted in the past should also be submitted.

*Participant Selection:* Please note that the winning applicant must consult closely with the Public Affairs Offices at the respective U.S. embassies during program implementation. Embassies will nominate participants for the program.

The Bureau anticipates funding no more than three grants for this theme, averaging approximately $180,000 each. There will be a total of approximately 40 participants funded through this RFGP. Each proposal should accommodate approximately 12–15 participants and should be regional in focus. ECA will consider proposals that include several distinct exchanges during the life of the grant, but all exchange groups should include participants from at least three countries.

Tentative participant numbers and needs are:

*Albania:* Four participants. English-speakers only.

*Bosnia-Herzegovina:* Four participants. Two English and two non-English speakers.

*Bulgaria:* Five participants.

*Croatia:* Four participants. English-speakers only.

*Macedonia:* Twelve participants. Six English and six non-English speakers.

*Serbia and Montenegro:* Fourteen participants. Seven English and seven non-English speakers.

Once projects are funded, ECA will work with the grantees to solicit more detailed information on the needs and interests of individual participants.

**Prevention of Trafficking in Persons in Southeastern Europe**

*Albania, Bosnia-Herzegovina, Bulgaria, Croatia, Macedonia, Romania, Serbia and Montenegro, Kosovo—Multi-Country Projects for all Nine Countries/ Regions Only*

Trafficking in persons continues to be a widespread problem in Southeastern Europe (SEE). In June 2002 the United States Department of State released its second report on the issue of trafficking in persons worldwide. (Please see *http://www.state.gov/g/tip/rls/tiprpt/2002/*.) Many SEE countries included in the study are classified as countries that have not taken adequate steps to quell trafficking in persons or to recognize the severity of the problem. The need to educate and inform communities and lawmakers has become imperative to prevent trafficking in the SEE region.

The Bureau seeks proposals that provide training to individuals and communities in the SEE region to help combat trafficking in persons. Programs should be regional in focus and should include cross-border efforts to ensure integration of efforts and cooperation among SEE countries. To avoid duplication of initiatives, applicants should be familiar with international organizations' programs and indigenous SEE non governmental organizations' (NGO) programs to combat trafficking. Applicants should outline relevant thematic and regional expertise in the proposal. Priority will be given to programs that propose to reach high-risk groups where anti-trafficking initiatives have been limited or nonexistent. Proposals must include a timeline for the entire grant period, a schedule for each program activity, subcontract agreements, resumes of trainers and proposed personnel, and letters of support from SEE and U.S. partners. Proposals may address either of the themes listed below. To be competitive, proposals should outline how participants will be selected. Participants should be from the SEE countries listed above and should be afforded networking and information sharing opportunities throughout the grant period. Priority should be given to foreign participants who have not traveled to the U.S. previously. Language and interpreting issues should also be addressed in the proposal. Applicants should expect to work closely with the Public Affairs Sections of the U.S. Embassies in SEE on coordination of all activities, including participant selection.

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character. Proposals must demonstrate an understanding of the principles behind the Trafficking Victims Protection Act of 2000 (the ''ACT'') and current U.S. government policy, as expressed through Trafficking in Persons National Security Presidential Directive of 2/2/5/03 (*http://www.whitehouse.gov/news/releases/2003/02/20030225.html*) and Executive Order 13257 (*http://nodis3.gsfc.nasa.gov/library/displayEO.cfm?id=EO_13257* )

*Areas of focus:*

(1) Two-way exchanges and training programs that may address public awareness, victim assistance, reintegration and/or occupational training.

The Bureau is seeking two-way exchange programs that will educate the U.S. and SEE citizenries on the issue of trafficking. Many nongovernmental organizations (NGOs) in SEE have been confronting the issue of trafficking and have much to share with their U.S. counterparts. (Given that many women are now being trafficked into the United States, it is important that U.S. relief and assistance organizations are exposed to effective prevention and assistance programs in SEE.) SEE participants in turn will benefit from exposure to U.S. models for job training and life skills management programs, peer education and economic assistance programs as well as models for successful advocacy and fundraising

campaigns on the issue. Participants may be leaders of NGOs, associations, community leaders, teachers and school administrators and local government officials. Follow-up workshops/on site consultations in the region are encouraged after the U.S.-based training. Programs may focus on developing participants' skills to establish job training programs in the region, but funding may not be used for the establishment or maintenance of victims' assistance centers or equipment for such centers. Successful proposals will offer hands-on training, including shadowing and internship opportunities, as well as the development of public awareness campaigns, action plans, publications, web-based information and/or other products that can be accessed easily by the general public and the respective SEE governments.

(2) Training and exchanges for members of parliament (particularly women members), ministry officials, government press spokespeople and local government officials.

The Bureau welcomes proposals that will encourage members of parliament, ministry officials, government press spokespeople and local government officials to take an active stand against trafficking in the SEE region.

Proposals should focus on how government should enforce and/or improve laws or national action plans against trafficking. Proposals should outline a strategy on how governments in the region can increase information sharing and close down trafficking routes in the region. Proposals should also address specifically how training will encourage cooperative and complementary efforts between the government and NGO community regarding the issue. U.S.-based exchanges and follow-up workshops in the region are strongly encouraged. The Bureau is interested in results-oriented proposals that include regional action planning, publications and other work products that will serve to educate government officials and the general public in the SEE region regarding trafficking.

*Project Funding*

The total funding available for prevention of trafficking programs is approximately $500,000. The Bureau anticipates awarding two or three proposals for this competition averaging approximately $165,00–$250,000 each.

**Anti-Corruption and Ethics**

*Latvia, Lithuania, and Estonia (Multi-Country Project for All Three Countries Only)*

The Bureau welcomes proposals for a regional anti-corruption program, designed to improve ethics oversight and management laws and procedures in the Baltic States. The Baltic nations continue to struggle against corruption at various levels of society. Government officials and law enforcement are poorly trained to recognize conflict of interest issues. In addition, ethical codes of conflict and conflict of interest legislation are weak. Unfortunately, influence peddling and conflict of interest can be found at the highest levels. Government employees deal with low salaries; difficult working conditions; lack of support from political leaders and senior administrators; and out-of-date equipment and records.

Citizens have low expectations for government service and can be inclined to view bribes at low levels or embezzlement, conflicts of interest and bribe-taking at high levels as the norm, to be tolerated rather than fought. Education is needed for both the public and civil servants/law enforcement on what each can expect of the other.

Proposals should outline a program that will train both Baltic officials and non-governmental personnel in government ethics issues and their respective roles in guaranteeing adherence to high standards of government ethics. The overall objectives of proposed programs should be to improve ethics oversight and management laws, policies, procedures and institutions in the Baltic states; increase public confidence in governmental institutions by training Baltic officials and non-governmental entities in government ethics issues as well as the role and responsibility of private citizens, the media and the academic community in guaranteeing high standards of government ethics.

Target populations for these programs include: members of Parliament, parliament staff and law enforcement officers responsible for enforcing conflict of interest/corruption legislation, national and municipal officials, government and civics professors from universities, NGO leaders, and media representatives. Proposals should describe a program that engages participants in relevant ethics issues, including the role of public ethics in a democratic society, ethics responsibilities for government officials, and the role of NGOs in monitoring public ethics and corruption.

ECA is looking for programs that include a mix of participants from different governmental and non-governmental institutions to ensure sharing of diverse experiences and build mutual understanding of common public ethics standards. Travel in both directions, including a hands-on, U.S.-based program with a train-the-trainer component, should be proposed. Continuous communication, mentoring, and consultations between overseas participants and trainers/mentors, should be described in detail and conducted throughout the life of the grant. Overseas, programs should be conducted in the form of short courses and include an appropriate public relations component (developed in coordination with U.S. embassies), to highlight the importance of anti-corruption efforts. Proposals should include a programming element that will bring participants from all three countries together to increase the program's regional impact.

*Project funding:* The total funding available for prevention of trafficking programs is approximately $200,000. The Bureau anticipates awarding one grant for this topic.

**Overall Budget Guidelines**

Grants awarded to eligible organizations with less than four years of experience in conducting international exchange programs will be limited to $60,000.

Applicants must submit a comprehensive budget for the entire program. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification. Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

Since Bureau grant assistance constitutes only a portion of total project funding, proposals should list and provide evidence of other anticipated sources of financial and in-kind support. While there is no minimum requirement, applicants are encouraged to provide cost sharing to the fullest extent possible. State Department Review Panels will consider cost sharing seriously when evaluating all proposals.

The following program costs are eligible for funding consideration:

1. *Travel Costs.* International and domestic airfares (per the Fly America Act), transit costs, ground transportation

costs, and visas for U.S. participants (J–1 visas for Bureau-supported participants from Eurasia to travel to the U.S. are issued at no charge).

2. *Per Diem.* For U.S.-based programming, organizations should use the published Federal per diem rates for individual U.S. cities. For activities in Europe/Eurasia, the Bureau strongly encourages applicants to budget realistic costs that reflect the local economy. Domestic per diem rates may be accessed at: *http://www.policyworks.gov/* and foreign per diem rates can be accessed at: *http://www.state.gov/www/perdiems/index.html.*

3. *Interpreters.* Local interpreters with adequate skills and experience may be used for program activities. The Bureau strongly encourages applicants to use local interpreters. Salary costs for local interpreters must be included in the budget. Costs associated with using their services may not exceed rates for U.S. Department of State interpreters. Typically, one interpreter is provided for every four visitors who require interpreting, with a minimum of two interpreters. Bureau grants do not pay for foreign interpreters to accompany delegations from their home country. U.S. Department of State Interpreters may be used if local interpreters are not available. Proposal budgets should contain a flat $170/day per diem for each U.S. Department of State interpreter, as well as home-program-home air transportation of $400 per interpreter, reimbursements for taxi fares, plus any other transportation expenses during the program. Salary expenses are covered centrally and should not be part of an applicant's proposed budget.

4. *Book and cultural allowance.* Foreign participants are entitled to a one-time cultural allowance of $150 per person, plus a book allowance of $50. Interpreters should be reimbursed up to $150 for expenses when they escort participants to cultural events. U.S. program staff, trainers or participants are not eligible to receive these benefits.

5. *Consultants.* Consultants may be used to provide specialized expertise or to make presentations. Daily honoraria cannot exceed $250 per day. Subcontracting organizations may also be used, in which case the written agreement between the prospective grantee and subcontractor should be included in the proposal. Subcontracts should be itemized in the budget.

6. *Room rental.* Room rental may not exceed $250 per day.

7. *Materials development.* Proposals may contain costs to purchase, develop and translate materials for participants. The Bureau strongly discourages the use of automatic translation software for the preparation of training materials or any information distributed to the group of participants or network of organizations. Costs for high-quality translation of materials should be anticipated and included in the budget. Grantee organizations should expect to submit a copy of all program materials to the Bureau.

8. *Equipment.* Proposals may contain costs to purchase equipment for Eurasia-based programming such as computers, fax machines and copy machines. Costs for furniture are not allowed. Equipment costs must be kept to a minimum.

9. *Working meal.* Only one working meal may be provided during the program. Per capita costs may not exceed $5–8 for a lunch and $14–20 for a dinner, excluding room rental.

The number of invited guests may not exceed participants by more than a factor of two-to-one. Interpreters must be included as participants.

10. *Return travel allowance.* A return travel allowance of $70 for each foreign participant may be included in the budget. The allowance may be used for incidental expenses incurred during international travel.

11. *Health Insurance.* Foreign participants will be covered under the terms of a Bureau-sponsored health insurance policy. The premium is paid by the Bureau directly to the insurance company. Applicants are permitted to include costs for travel insurance for U.S. participants in the budget.

12. *Wire transfer fees.* When necessary, applicants may include costs to transfer funds to partner organizations overseas.

13. *Administrative Costs.* Costs necessary for the effective administration of the program may include salaries for grantee organization employees, benefits, and other direct and indirect costs per detailed instructions in the Application Package. While there is no rigid ratio of administrative to program costs, priority will be given to proposals whose administrative costs are less than twenty-five (25) per cent of the total requested from the Bureau. Proposals should show strong administrative cost-sharing contributions from the applicant, the in-country partner and other sources.

**Deadline for Proposals**

All proposal copies must be received at the Bureau of Educational and Cultural Affairs by 5 p.m. Washington, DC time on Friday, May 9, 2003. Faxed documents will not be accepted at any time. Documents postmarked the due date but received on a later date will not be accepted. Each applicant must ensure that the proposals are received by the above deadline.

Applicants must follow all instructions in the Solicitation Package. The original and twelve copies of the application should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: ECA/PE/C/EUR–03–39, Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

**Diversity, Freedom and Democracy Guidelines**

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. ''Diversity'' should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and physical challenges. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the ''Support for Diversity'' section for specific suggestions on incorporating diversity into the total proposal. Public Law 104–319 provides that ''in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy, ''the Bureau'' shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries.'' Public Law 106—113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

**Review Process**

The Bureau will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be

reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards resides with the Bureau's Grants Officer.

**Review Criteria**

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Program Planning and Ability to Achieve Program Objectives:* Program objectives should be stated clearly and should reflect the applicant's expertise in the subject area and region. Objectives should respond to the priority topics in this announcement and should relate to the current conditions in the target countries. A detailed agenda and relevant work plan should explain how objectives will be achieved and should include a timetable for completion of major tasks. The substance of workshops, internships, seminars and/or consulting should be described in detail. Sample training schedules should be outlined. Responsibilities of in-country partners should be clearly described.

2. *Institutional Capacity:* The proposal should include (1) the U.S. institution's mission and date of establishment (2) detailed information about the in-country partner institution's capacity and the history of the U.S. and in-country partnership (3) an outline of prior awards—U.S. government and private support received for the target theme/region (4) descriptions of experienced staff members who will implement the program. Proposed personnel and institutional resources should be adequate and appropriate to achieve the program's goals. The proposal should reflect the institution's expertise in the subject area and knowledge of the conditions in the target country. Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau grants as determined by Bureau Grant Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

3. *Cost Effectiveness and Cost Sharing:* Overhead and administrative costs for the proposal, including salaries, honoraria and subcontracts for services, should be kept to a minimum. Priority will be given to proposals whose administrative costs are less than twenty-five (25) per cent of the total funds requested from the Bureau. Applicants are encouraged to cost share a portion of overhead and administrative expenses. Cost-sharing, including contributions from the applicant, the in-country partner, and other sources should be included in the budget request.

4. *Support of Diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (selection of participants, program venues and program evaluation) and program content (orientation and wrap-up sessions, program meetings, resource materials and follow-up activities). Applicants should refer to the Bureau's Diversity, Freedom and Democracy Guidelines in the Proposal Submission Instructions (PSI).

5. *Follow-on Activities:* Proposals should provide a plan for continued follow-on activity (without Bureau financial support) ensuring that Bureau supported programs are not isolated events.

6. *Evaluation:* Proposals should include a detailed plan to monitor and evaluate the program. A draft survey questionnaire plus a description of a methodology to use to link outcomes to original project objectives should be included. Successful applicants will be expected to submit intermediate reports after each project component concludes or on a quarterly basis, whichever is less frequent.

**Authority**

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is ''to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.'' The funding authority for the program above is provided through legislation. The funding authority for this program is provided through the Support for East European Democracies (SEED) Act of 1989.

**Notice**

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements.

**Notification**

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures.

Dated: March 6, 2003.

**C. Miller Crouch,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 03–6083 Filed 3–12–03; 8:45 am]

BILLING CODE 4710–05–P

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## DEPARTMENT OF STATE

**[Public Notice 4296]**

## Bureau of Educational and Cultural Affairs Request for Grant Proposals: Fulbright Teacher and Administrator Exchange Program

**SUMMARY:** The Office of Global Educational Programs of the Bureau of Educational and Cultural Affairs (ECA) announces an open competition to administer the Fulbright Teacher and Administrator Exchange Program. Public and private non-profit organizations meeting the provisions described in Internal Revenue Code section 26 U.S.C. 501(c)(3) may submit proposals.

**Program Information**

*Overview:* The Fulbright Teacher and Administrator Program provides opportunities for elementary and secondary teachers, administrators, and other school or community college faculty to participate in direct exchanges of positions with colleagues from other countries for six weeks, a semester, or a full academic year.

The program provides a rich professional growth opportunity while enhancing mutual understanding among foreign and U.S. teachers, administrators, their students, and host

communities. The major program components include alumni relations, recruitment and outreach, participant matching, orientation of U.S. and foreign participants, administration of training and professional meeting programs of the Fall and Spring workshops, and monitoring and evaluation protocols. The cooperating agency must maintain a flexible approach in response to changing program needs and priorities. Effective and direct communications between the cooperating agency and ECA's Teacher Exchange Branch will be necessary at all times. Consequently, the cooperating agency is required to have a Washington, D.C.-based office to facilitate communication. A detailed listing of responsibilities is provided in the Project Objectives, Goals, and Implementation (POGI) document and should be consulted in preparing the proposal.

*Alumni Development*

Alumni program initiatives should emphasize the development of the program's alumni groups throughout the United States. The cooperating agency will provide support to individual U.S. alumni and assist them in developing their respective alumni groups. Alumni groups may develop small projects funded through this grant to enhance the program, such as school-to-school partnerships, etc. In addition, data collection and operation of a database of grantees and alumni, with subject fields defined by the Branch, will be required, and must be compatible with the Bureau's Academic Exchange Information System dbase (AEIS).

*Recruitment and Outreach*

The cooperating agency is responsible for recruitment of U.S. program participants (teachers and administrators) through a nation-wide recruitment campaign. Selection is based on teachers' and administrators' professional background and leadership potential. Foreign exchange participants are recruited and nominated by U.S. embassies or overseas Fulbright Commissions. To qualify for the program, applicants must have a minimum of three years professional experience, hold an equivalent full-time teaching position and a Bachelor's degree or higher, and be fluent in English.

The cooperating agency will submit a yearly recruitment and outreach plan to the Branch and will be responsible for all recruitment activities including attendance at conferences, mass mailings of promotional materials, responses to general inquires, web site development, and creating and updating handbooks.

*Matching*

The cooperating agency forwards all U.S. candidates who are interviewed by volunteer peer review committees. After that step the U.S. applicants are matched with foreign partners whose professional and personal backgrounds are congruent with the backgrounds of their American partners. For example, elementary teachers are matched with elementary teachers and secondary school math teachers with like professional counterparts in an eligible foreign country. The cooperating agency simultaneously forwards candidate dossiers to over 30 countries for consideration. The dossiers are evaluated and matched by overseas counterparts, such as the Fulbright Commission, the public affairs section of the U.S. Embassy, or an in-country hosting organization, depending upon the circumstances in country. All final matches must be mutually agreed upon by all U.S. and overseas counterparts. The Teacher Exchange Branch will play a coordinating role in this process and liaise between the U.S. cooperating agency and the overseas counterpart.

*Professional Meeting Program*

Regional meetings for foreign teachers participating in the program are held at seven locations in the United States in the Fall of each academic year and are designed to stimulate the teachers to discuss and think through the challenges of adjusting to teaching and living in the United States In addition, Spring meetings are held in 12 to 15 regional sites in the United States, to debrief the foreign teachers as well as prepare them for re-entry to their home countries. U.S. teachers selected for the upcoming program year will also attend the Spring meetings in preparation for their overseas exchange. The cooperating agency will be responsible for obtaining local administrative and program support for both Fall and Spring meetings and will assist in staffing a portion of the meetings.

*Orientation*

Approximately 530 U.S. and foreign Fulbright Teacher Exchange Program participants and their family members attend an orientation program in Washington, DC in the Summer, prior to their exchange year. The orientation will provide the participants with opportunities to meet one-on-one prior to their reciprocal exchanges. The cooperating agency will organize the orientation; activities include formal presentations and workshops on educational and cross-cultural issues that will help prepare participants for their year or semester abroad.

*Monitoring*

During the academic year, the cooperating agency monitors the professional and personal well-being of the foreign teachers. Staff members from the cooperating organization monitor the performance of participants and counsel foreign participants, if needed, at the Fall and Spring meetings. The cooperating agency will staff a full-time position solely for monitoring and supporting program participants. The cooperating agency consults with Branch staff and provides written reports on any issue that may adversely affect an exchange or the program in general.

*Other Administrative Support*

The cooperating agency is expected to provide extensive support to the Teacher and Administrator Exchange Program. Bi-monthly meetings, and other meetings pertaining to the grant's core program components, will be held between the Branch and the cooperating agency on a regular basis. The cooperating agency will also be responsible for maintaining telephone, e-mail, and fax communications with appropriate Branch and ECA staff. Other administrative services to be provided by the cooperating agency include: paying stipends to and withholding taxes for selected foreign grantees; and supporting special projects.

*Evaluation*

The cooperating agency will be responsible for developing, collecting, analyzing, and disseminating means of participant evaluation for workshops and the orientation, and developing a summative program evaluation at the end of each academic year. The evaluation of these activities will include, but not be limited to, an assessment of the effectiveness of each of the program components and may include suggestions for program improvement and innovation.

*Guidelines*

Pending availability of funds, the grant will begin on October 1, 2003 and will run through September 30, 2006. The administrative portion of the grant will only cover October 1, 2003 to September 30, 2004. U.S. program participants will be recruited nationwide and from the full range of the teaching profession from primary to the community college level. The cooperating agency will also provide support for approximately 175 foreign

teachers and administrators from approximately 30 countries. Contingent upon satisfactory performance based on annual reviews, the Bureau intends to renew the award each year for a period of not less than four additional years.

Programs must comply with J–1 visa regulations. Please refer to the Solicitation Package for further information.

**Budget Guidelines**

The Bureau anticipates awarding one grant in the amount of $2.3 million to support program and administrative costs required to implement this program. Bureau grant guidelines require that organizations with less than four years experience in conducting international exchanges be limited to $60,000 in Bureau funding. Therefore, organizations that cannot demonstrate at least four years experience in conducting international exchanges are ineligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost-sharing and funding from private sources in support of its programs.

Applicants must submit a comprehensive budget for the entire program. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification. Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

*Announcement Title and Number:* All correspondence with the Bureau concerning this RFGP should reference the above title and number ECA/A/S/X–04–01.

**FOR FURTHER INFORMATION CONTACT:** The Office of Global Educational Programs, ECA/A/S/X, Room Number 349, U.S. Department of State, SA–44, 301 4th Street, SW., Washington, DC 20547, 202 619–4555 or fax 202 401-1433, *mpizarro@pd.state.gov* to request a Solicitation Package. The Solicitation Package contains detailed award criteria, required application forms, specific budget instructions, and standard guidelines for proposal preparation. Please specify Bureau Senior Program Officer Mary Lou Johnson-Pizarro on all other inquiries and correspondence.

Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

*To Download a Solicitation Package via Internet:* The entire Solicitation Package may be downloaded from the Bureau's Web site at *http://exchanges.state.gov/education/RFGPs.* Please read all information before downloading.

*Deadline for Proposals:* All proposal copies must be received at the Bureau of Educational and Cultural Affairs by 5 p.m. Washington, DC time on May 2, 2003. Faxed documents will not be accepted at any time. Documents postmarked the due date but received on a later date will not be accepted. Each applicant must ensure that the proposals are received by the above deadline.

Applicants must follow all instructions in the Solicitation Package. The original and eight copies of the application should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: ECA/A/S/X–04–01, Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

**Diversity, Freedom and Democracy Guidelines**

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. ''Diversity'' should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and physical challenges. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into the total proposal. Public Law 104–319 provides that ''in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy,'' the Bureau ''shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries.''

Public Law 106—113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

**Adherence to All Regulations Governing the J Visa**

The Bureau of Educational and Cultural Affairs is placing renewed emphasis on the secure and proper administration of Exchange Visitor (J visa) Programs and adherence by grantees and sponsors to all regulations governing the J visa. Therefore, proposals should demonstrate the applicant's capacity to meet all requirements governing the administration of Exchange Visitor Programs as set forth in 22 CFR 6Z, including the oversight of Responsible Officers and Alternate Responsible Officers, screening and selection of program participants, provision of pre-arrival information and orientation to participants, monitoring of participants, proper maintenance and security of forms, record-keeping, reporting and other requirements. The Grantee will be responsible for issuing DS–2019 forms to participants in this program.

A copy of the complete regulations governing the administration of Exchange Visitor (J) programs is available at *http://exchanges.state.gov* or from: United States Department of State, Office of Exchange Coordination and Designation, ECA/EC/ECD—SA–44, Room 734, 301 4th Street, SW., Washington, DC 20547, Telephone: (202) 401–9810, FAX: (202) 401–9809.

**Review Process**

The Bureau will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office and will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards cooperative agreement resides with the Bureau's Grants Officer.

**Review Criteria**

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Quality and Clarity of the Program planning:* Proposals should exhibit originality, substance, precision, and

relevance to the Bureau's mission. Detailed agenda and relevant work plan should demonstrate substantive undertakings and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above.

2. *Support of Diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (selection of participants, program venue and evaluation) and program content (orientation, workshops and wrap-up sessions, resource materials and follow-up activities).

3. *Ability to achieve program objectives:* Objectives should be reasonable, feasible, and flexible. Proposals should clearly demonstrate how the institution will meet the program's objectives and plan.

4. *Institutional Capacity:* Proposed personnel and institutional resources should be adequate and appropriate to achieve the program or project's goals. Proposals should demonstrate an institutional record of successful program planning and implementation, including responsible fiscal management and full compliance with all reporting requirements.

5. *Project Evaluation:* Proposals should include a plan to evaluate the activity's success, both as the activities unfold and at the end of the program. A draft survey questionnaire or other technique plus description of a methodology to use to link outcomes to original project objectives are recommended. Successful applicants will be expected to submit intermediate reports after each project component is concluded or quarterly, whichever is less frequent.

6. *Cost-effectiveness and Cost-sharing:* The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate. Proposals should maximize cost sharing through other private sector support as well as institutional direct funding contributions.

**Authority**

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is ''to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.'' The funding authority for the program above is provided through legislation.

**Notice**

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements.

**Notification**

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures.

Dated: March 5, 2003.

**C. Miller Crouch,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

[FR Doc. 03–5762 Filed 3–12–03; 8:45 am]

BILLING CODE 4710–05–P

## DEPARTMENT OF STATE

**[Public Notice 4270]**

### Notice of Meeting: United States International Telecommunication Advisory Committee Preparations for ITU Development Sector Meetings

The Department of State announces meetings of the U.S. International Telecommunication Advisory Committee (ITAC). The purpose of the Committee is to advise the Department on policy, technical and operational issues with respect to international telecommunications standardization bodies such as the International Telecommunication Union. The ITAC for ITU–T Study Group 3 will meet from 2–4 pm March 19 at the Federal Communications Commission; ITAC for ITU–T TSAG will meet March 26 from 9:30–4 pm at INTELSAT (3400 International Drive, NW., Washington, DC, 7th Floor.

Press of business and recent weather delays and closing has been the cause of short notice.

Dated: March 7, 2003.

**Marian Gordon,**

*Director, Telecommunication Development, Department of State.*

[FR Doc. 03–6082 Filed 3–12–03; 8:45 am]

BILLING CODE 4710–45–P

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Trade Policy Staff Committee; Initiation of Environmental Review of Australia Free Trade Negotiations; Public Comments on Scope of Environmental Review

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice and request for comments.

**SUMMARY:** This publication gives notice that, pursuant to the Trade Act of 2002, and consistent with Executive Order 13141 (64 FR 63169) (Nov. 18, 1999) and its implementing guidelines (65 FR 79442), the Office of the United States Trade Representative (USTR), through the Trade Policy Staff Committee (TPSC), is initiating an environmental review of the proposed United States-Australia Free Trade Agreement. The TPSC is requesting written comments from the public on what should be included in the scope of the environmental review, including the potential environmental effects that might flow from the free trade agreement and the potential implications for U.S. environmental laws and regulations, and identification of complementarities between trade and environmental objectives such as the promotion of sustainable development. The TPSC also welcomes public views on appropriate methodologies and sources of data for conducting the review. Persons submitting written comments should provide as much detail as possible on the degree to which the subject matter they propose for inclusion in the review may raise significant environmental issues in the context of the negotiation.

**DATES:** Public comments should be received no later than April 30, 2003.

**ADDRESSES:** Submissions by electronic mail: FR0072@ustr.gov.

Submissions by facsimile: Gloria Blue, Executive Secretary, Trade Policy Staff Committee, at (202) 395–6143.

**FOR FURTHER INFORMATION CONTACT:** For procedural questions concerning public comments, contact Gloria Blue,

Executive Secretary, TPSC, Office of the USTR, 1724 F Street, NW., Washington, DC 20508, telephone (202) 395–3475. Questions concerning the environmental review should be addressed to David J. Brooks, Environment and Natural Resources Section, USTR, telephone (202) 395–7320.

**SUPPLEMENTARY INFORMATION:**

**1. Background Information**

On November 13, 2002, in accordance with section 2104(a)(1) of the Trade Act of 2002, the Untied States Trade Representative, Ambassador Robert B. Zoellick, notified Congress of the President's intent to enter into trade negotiations with Australia. Ambassador Zoellick outlined specific U.S. objectives for these negotiations in the notification letters to Congress. Copies of the letters are available at *http://www.ustr.gov/releases/2002/11/2002-11-13-australia-hastert.PDF* and *http://ww.ustr.gov/releases/2002/11/2002-11-13-australia-byrd.PDF*).

The TPSC invited the public to provide written comments and/or oral testimony at a public hearing that took place on January 15, 2003, to assist USTR in amplifying and clarifying negotiating objectives for the proposed FTA and to provide advice on how specific goods and services and other matters should be treated under the proposed agreement (67 FR 76431).

Two-way trade between the United States and Australia has grown significantly in the past decade, and totaled more than $19 billion in 2001. The increased access to Australia's market that an FTA would provide would further boost trade in both goods and services, enhancing employment opportunities in both countries. An FTA also would encourage additional foreign investment between the United States and Australia. A free trade agreement with Australia would further deepen the already close cooperation between the United States and Australia in advancing objectives for multilateral negotiations currently underway in the World Trade organization (WTO).

**2. Environmental Review**

USTR, through the TPSC, will perform an environmental review of the agreement pursuant to the Trade Act of 2002 and consistent with Executive Order 13141 (64 FR 63169) and its implementing guidelines (65 FR 79442).

Environmental reviews are used to identify potentially significant, reasonable foreseeable environmental impacts (both positive and negative), and information from the review can help facilitate consideration of appropriate responses where impacts are identified. Reviews address potential environmental impacts of the proposed agreement and potential implications for environmental laws and regulations. The focus of the review is on impacts in the United States, although global and transboundary impacts may be considered, where appropriate and prudent.

**3. Requirements for Submissions**

In order to facilitate prompt processing of submissions, USTR strongly urges and prefers electronic (e-mail) submissions in response to this notice.

Persons making submission by e-mail should use the following subject line: ''United States—Australia FTA Environmental Review'' followed by ''Written Comments.'' Documents should be submitted as either WordPerfect, MSWord, or text (.TXT) files. Supporting documentation submitted as spreadsheets are acceptable as Quattro Pro or Excel. For any document containing business confidential information submitted electronically, the file name of the business confidential version should begin with the characters ''BC-'', and the file name of the public version should begin with the characters ''P-''. The ''P-'' or ''BC-'' should be followed by the name of the submitter. Persons who make submissions by e-mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. To the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Written comments submitted in response to this request will be placed in a file open to public inspection pursuant to 15 CFR 2003.5, except business confidential information exempt from public inspection in accordance with 15 CFR 2003.6. Business confidential information submitted in accordance with 15 CFR 2003.6 must be clearly marked ''BUSINESS CONFIDENTIAL'' at the top of each page, including any cover letter or cover page, and must be accompanied by a nonconfidential summary of the confidential information. All public documents and nonconfidential summaries shall be available for public inspection in the USTR Reading Room. The USTR Reading Room is open to the public, by appointment only, from 10 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday. An appointment to review the file must be scheduled at least 48 hours in advance and may be made by calling (202) 395–6186.

USTR also welcomes and will take into account the public comments on Australia FTA environmental issues submitted in response to a previous notice—the **Federal Register** notice dated December 12, 2002 (67 FR 76431)—requesting comments from the public to assist USTR in formulating positions and proposals with respect to all aspects of the negotiations, including environmental issues. These comments will also be made available for public inspection.

General information concerning the Office of the United States Trade Representative may be obtained by accessing its Internet website (*http://www.ustr.gov*).

**Carmen Suro-Bredie,**

*Chair, Trade Policy Staff Committee.*

[FR Doc. 03–5990 Filed 3–12–03; 8:45 am]

**BILLING CODE 3190–01–M**

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## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Trade Policy Staff Committee; Initiation of Environmental Review of Free Trade Negotiations with the Southern African Customs Union; Public Comments on Scope of Environmental Review

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice and request for comments.

**SUMMARY:** This publication gives notice that, pursuant to the Trade Act of 2002, and consistent with Executive Order 13141 (64 FR 63169) (Nov. 18, 1999) and its implementing guidelines (65 FR 79442), the Office of the United States Trade Representative (USTR), through the Trade Policy Staff Committee (TPSC), is initiating an environmental review of the proposed United States-Southern African Customs Union Free Trade Agreement (U.S–SACU FTA). The TPSC is requesting written comments from the public on what should be included in the scope of the environmental review, including the potential environmental effects that might flow from the free trade agreement and the potential implications for U.S. environmental laws and regulations, and identification of complementarities between trade and environmental objectives such as the promotion of sustainable development. The TPSC also welcomes public views on appropriate methodologies and sources of data for conducting the review. Persons submitting written

comments should provide as much detail as possible on the degree to which the subject matter they propose for inclusion in the review may raise significant environmental issues in the context of the negotiation.

**DATE:** Public comments should be received no later than April 30, 2003.

**ADDRESSES:** Submissions by electronic mail:

*FR0073@ustr.gov.*

*Submissions by facsimile:* Gloria Blue, Executive Secretary, Trade Policy Staff Committee, at (202) 395–6143.

**FOR FURTHER INFORMATION CONTACT:** For procedural questions concerning public comments, contact Gloria Blue, Executive Secretary, TPSC, Office of the USTR, 1724 F Street, NW., Washington, DC 20508, telephone (202) 395–3475. Questions concerning the environmental review should be addressed to David J. Brooks, Environment and Natural Resources Section, USTR, telephone (202) 395–7320.

**SUPPLEMENTARY INFORMATION:**

**1. Background**

On November 4, 2002, in accordance with section 2104(a)(1) of the Trade Act of 2002, the United States Trade Representative, Ambassador Robert B. Zoellick, notified Congress of the President's intent to enter into trade negotiations with the member nations of the Southern African Customs Union (SACU): Botswana, Lesotho, Namibia, South Africa, and Swaziland. Ambassador Zoellick outlined specific U.S. objectives for these negotiations in the notification letters to Congress. Copies of the letters are available at *http://www.ustr.gov/releases/2002/11/2002–11–04–SACU–byrd.PDF* and *http://www.ustr.gov/releases/2002/11/2002–11–04–SACU–hastert.PDF.*

The TPSC invited the public to provide written comments and/or oral testimony at a public hearing that took place on December 16, 2002, to assist USTR in amplifying and clarifying negotiating objectives for the proposed FTA and to provide advice on how specific goods and services and other matters should be treated under the proposed agreement (67 FR 69295).

A free trade agreement with SACU would deepen economic and political ties to sub-Saharan Africa and lend momentum to development efforts for the region. SACU is the largest U.S. export market in sub-Saharan Africa, accounting for approximately $3.1 billion in exports in 2001. Total two-way trade in goods between the United States and the member countries of SACU totaled $7.9 billion in 2001. Leading U.S. exports to SACU include machinery and equipment, aircraft, vehicles, chemicals, plastics and agricultural products. Leading U.S. imports from SACU include vehicles, minerals, precious stones and metals, iron and steel products, and apparel.

**2. Environmental Review**

USTR, through the TPSC, will perform an environmental review of the agreement pursuant to the Trade Act of 2002 and consistent with Executive Order 13141 (64 FR 63169) and its implementing guidelines (65 FR 79442).

Environmental reviews are used to identify potentially significant, reasonably foreseeable environmental impacts (both positive and negative), and information from the review can help facilitate consideration of appropriate responses where impacts are identified. Reviews address potential environmental impacts of the proposed agreement and potential implications for envionmental laws and regulations. The focus of the review is on impacts in the United States, although global and transboundary impacts may be considered, where appropriate and prudent.

**3. Requirements for Submissions**

In order to facilitate prompt processing of submissions, USTR strongly urges and prefers electronic (e-mail) submissions in response to this notice.

Persons making submissions by e-mail should use the following subject line: ''U.S.–SACU FTA Environmental Review'' followed by ''Written Comments.'' Documents should be submitted as either WordPerfect, MSWord, or text (.TXT) files. Supporting documentation submitted as spreadsheets are acceptable as Quattro Pro or Excel. For any document containing business confidential information submitted electronically, the file name of the business confidential version should begin with the characters ''BC-'', and the file name of the public version should begin with the characters ''P-''. The ''P-'' or ''BC-'' should be followed by the name of the submitter. Persons who make submissions by e-mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. To the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Written comments submitted in response to this request will be placed in a file open to public inspection pursuant to 15 CFR 2003.5, except business confidential information exempt from public inspection in accordance with 15 CFR 2003.6. Business confidential information submitted in accordance with 15 CFR 2003.6 must be clearly marked ''BUSINESS CONFIDENTIAL'' at the top of each page, including any cover letter or cover page, and must be accompanied by a nonconfidential summary of the confidential information. All public documents and nonconfidential summaries shall be available for public inspection in the USTR Reading Room. The USTR Reading Room is open to the public, by appointment only, from 10 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday. An appointment to review the file must be scheduled at least 48 hours in advance and may be made by calling (202) 395–6186.

USTR also welcomes and will take into account the public comments on U.S.–SACU FTA environmental issues submitted in response to a previous notice—the **Federal Register** notice dated November 15, 2002 (67 FR 69295)—requesting comments from the public to assist USTR in formulating positions and proposals with respect to all aspects of the negotiations, including environmental issues. These comments will also be made available for public inspection.

General information concerning the Office of the United States Trade Representative may be obtained by accessing its Internet website (*http://www.ustr.gov*).

**Carmen Suro-Bredie,**

*Chair, Trade Policy Staff Committee.*

[FR Doc. 03–5991 Filed 3–12–03; 8:45 am]

BILLING CODE 3190–01–P

## DEPARTMENT OF THE TREASURY

### Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service

**AGENCY:** Departmental Offices, Treasury.

**ACTION:** Notice of meeting and announcement of membership.

**SUMMARY:** This notice announces the date, time, and location for the second meeting of the eighth term of the Treasury Advisory Committee on Commercial Operations (COAC), and the provisional agenda for consideration by the Committee.

**DATES:** The next meeting of the Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service will be held on Friday, April 4, 2003, at

9 a.m. at the U.S. Customs Service, in the Ronald Reagan Building, located at 13th Street and Pennsylvania Avenue, NW., Washington, DC. (Main entrance off of 14th Street) The duration of the meeting will be approximately four hours, starting at 9 a.m.

**FOR FURTHER INFORMATION CONTACT:** Robyn Day at 202–927–1440.

At this meeting, the Advisory Committee is expected to pursue the following agenda. The agenda may be modified prior to the meeting.

*Agenda:*

(1) Customs Business
(2) Customs Trade Partnership Against Terrorism, 24-hr. Manifest Rules, Customs Structure in Department of Homeland Security
(3) Merchandise Processing Fee; Proper Deduction of Freight & Other Costs from Customs Value
(4) OR&R
(5) Committee Administration
(6) Agenda Items for Next Meeting

**SUPPLEMENTARY INFORMATION:** The meeting is open to the public; however, participation in the Committee's deliberations is limited to Committee members, Customs and Treasury Department staff, and persons invited to attend the meeting for special presentations. A person other than an Advisory Committee member who wishes to attend the meeting should contact Robyn Day for pre-clearance.

Dated: March 7, 2003.

**Timothy E. Skud,**

*Deputy Assistant Secretary.*

[FR Doc. 03–6050 Filed 3–12–03; 8:45 am]

**BILLING CODE 4810–25–P**

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## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Surety Companies Acceptable on Federal Bonds: the American Road Insurance Company

**AGENCY:** Financial Management Service, Fiscal Service, Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** This is Supplement No. 10 to the Treasury Department Circular 570; 2002 Revision, published July 1, 2002, at 67 FR 44294.

**FOR FURTHER INFORMATION CONTACT:** Surety Bond Branch at (202) 874–6765.

**SUPPLEMENTARY INFORMATION:** A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued to the following Company under 31 U.S.C. 9304 to 9308. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570, 2002 Revision, on page 44299 to reflect this addition: The American Road Insurance Company. Business Address: The American Road, Dearborn, MI 48121–6027. Phone: (313) 337–1102. Underwriting Limitation b/: $26,143,000. Surety Licenses c/: AL, AK, AZ, AR, CA, CO, DE, DC, FL, GA, ID, IL, IN, IA, LA, ME, MD, MI, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI. Incorporated In: Michigan.

Certificates of Authority expire on June 30 each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (31 CFR part 223). A list of qualified companies is published annually as of July 1 in Treasury Department Circular 570, with details as to underwriting limitations, areas in which licensed to transact surety business and other information.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570/index.html.* A hard copy may be purchased from the Government Printing Office (GPO) Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04067–1.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F04, Hyattsville, MD 20782.

Dated: March 4, 2003.

**Wanda J. Rogers,**

*Director, Financial Accounting and Services Division, Financial Management Service.*

[FR Doc. 03–5960 Filed 3–12–03; 8:45 am]

**BILLING CODE 4810–35–M**

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## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Surety Companies Acceptable on Federal Bonds: Termination—Gerling Global Reinsurance Corporation of America

**AGENCY:** Financial Management Service, Fiscal Service, Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** This is Supplement No. 6 to the Treasury Department Circular 570; 2002 Revision, published July 1, 2002, at 67 FR 44294.

**FOR FURTHER INFORMATION CONTACT:** Surety Bond Branch at (202) 874–1033.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the Certificate of Authority issued by the Treasury to the above named Company, under the United States Code, title 31, sections 9304–9308, to qualify as an acceptable reinsurer on Federal bonds is terminated effective today.

The Company was last listed as an acceptable reinsurer on Federal bonds at 67 FR 44336, July 1, 2002.

With respect to any bonds currently in force with above listed Company, bond-approving officers should secure new bonds with acceptable reinsurers in those instances where a significant amount of liability remains outstanding. In addition, in no event, should bonds that are continuous in nature be renewed.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570/index.html.* A hard copy may be purchased from the Government Printing Office (GPO), Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04067–1.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F07, Hyattsville, MD 20782.

Dated: February 26, 2003.

**Judith R. Tillman,**

*Assistant Commissioner, Financial Operations, Financial Management Service.*

[FR Doc. 03–5964 Filed 3–12–03; 8:45 am]

**BILLING CODE 4810–35–M**

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## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Surety Companies Acceptable on Federal Bonds: Termination—Markel Insurance Company

**AGENCY:** Financial Management Service, Fiscal Service, Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** This is Supplement No. 7 to the Treasury Department Circular 570; 2002 Revision, published July 1, 2002, at 67 FR 44294.

**FOR FURTHER INFORMATION CONTACT:** Surety Bond Branch at (202) 874–6696.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the Certificate of Authority issued by the Treasury to the

above named Company, under the United States Code, title 31, sections 9304–9308, to qualify as an acceptable surety on Federal bonds is terminated effective today.

The Company was last listed as an acceptable surety on Federal bonds at 67 FR 44317, July 1, 2002.

With respect to any bonds currently in force with above listed Company, bond-approving officers may let such bonds run to expiration and need not secure new bonds. However, no new bonds should be accepted from the Company. In addition, bonds that are continuous in nature should not be renewed.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.* A hard copy may be purchased from the Government Printing Office (GPO), Subscription Service, Washington, DC, telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04067–1.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F07, Hyattsville, MD 20782.

Dated: February 26, 2003.

**Wanda J. Rogers,**

*Director, Financial Accounting and Services Division, Financial Management Service.*

[FR Doc. 03–5963 Filed 3–12–03; 8:45 am]

**BILLING CODE 4810–35–M**

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## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Surety Companies Acceptable on Federal Bonds: Star Insurance Company

**AGENCY:** Financial Management Service, Fiscal Service, Department of the Treasury.

**ACTION:** Notice.

**SUMMARY:** This is Supplement No. 8 to the Treasury Department Circular 570; 2002 Revision, published July 1, 2002, at 67 FR 44294.

**FOR FURTHER INFORMATION CONTACT:** Surety Bond Branch at (202) 874–7102.

**SUPPLEMENTARY INFORMATION:** A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued to the following Company under 31 U.S.C. 9304 to 9308. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570, 2002 Revision, on page 44328 to reflect this addition: Company Name: Star insurance Company. Business Address: 26600 Telegraph Road; Southfield, MI 48034. Phone: (248) 358–1100. Underwriting Limitation b/: $1,008,000. Surety Licenses c/: AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY. Incorporated in: Michigan.

Certificates of Authority expire on June 30 each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (31 CFR part 223). A list of qualified companies is published annually as of July 1 in Treasury Department Circular 570, with details as to underwriting limitations, areas in which licensed to transact surety business and other information.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.* A hard copy may be purchased from the Government Printing Office (GPO) Subscription Service, Washington, DC, Telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04067–1.

Questions concerning this Notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F07, Hyattsville, MD 20781.

Dated: February 21, 2003.

**Wanda Rogers,**

*Director, Financial Accounting and Services Division, Financial Management Service.*

[FR Doc. 03–5962 Filed 3–12–03; 8:45 am]

**BILLING CODE 4910–35–M**

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## DEPARTMENT OF THE TREASURY

### Fiscal Service

### Surety Companies Acceptable on Federal Bonds: U.S. Specialty Insurance Company

**AGENCY:** Financial Management Services, Fiscal Service, Department of the Treasury.

**ACTION:** Notice

**SUMMARY:** This is Supplement No. 9 to the Treasury Department Circular 570; 2002 Revision, published July 1, 2002, at 67 FR 44294.

**FOR FURTHER INFORMATION CONTACT:** Surety Bond Branch at (202) 874–7116.

**SUPPLEMENTARY INFORMATION:** A Certificate of Authority as an acceptable surety on Federal bonds is hereby issued to the following Company under 31 U.S.C. 9304 to 9308. Federal bond-approving officers should annotate their reference copies of the Treasury Circular 570, 2002 Revision, on page 44331 to reflect this addition: Company Name: U.S. Speciality Insurance Company. Business Address: 13403 Northwest Freeway, Houston, TX 77040–6006. Phone: (713) 744–3700. Underwriting Limitation b/: $5,433,000. Surety Licenses c/: AL, AK, AR, CO, DC, HI, ID, IL, KS, KY, LA, MS, MO, MT, NV, NM, NY, ND, OK, SD, TN, TX, VT, WA, WV, WY. Incorporated In: Texas.

Certificates of Authority expire on June 30 each year, unless revoked prior to that date. The Certificates are subject to subsequent annual renewal as long as the companies remain qualified (31 CFR part 223). A list of qualified companies is published annually as of July 1 in Treasury Department Circular 570, with details as to underwriting limitations, areas in which licensed to transact surety business sand other information.

The Circular may be viewed and downloaded through the Internet at *http://www.fms.treas.gov/c570.* A hard copy may be purchased from the Government Printing Office (GPO) Subscription Service, Washington, DC, Telephone (202) 512–1800. When ordering the Circular from GPO, use the following stock number: 769–004–04067–1.

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Financial Management Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F07, Hyattsville, MD 20782.

Dated: February 21, 2003

**Wanda J. Rogers,**

*Director, Financial Accounting and Services Division, Financial Management Service.*

[FR Doc. 03–5961 Filed 3–12–03; 8:45 am]

**BILLING CODE 4810–35–M**

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## DEPARTMENT OF VETERANS AFFAIRS

### Advisory Committee on Prosthetics and Special Disabilities Programs; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 that a meeting of the Advisory Committee on Prosthetics and Special Disabilities Programs will be held April 8–9, 2003, at VA Headquarters, 810 Vermont Avenue, NW., Washington,

DC. The meeting will be held in Room 430 on both days. Meeting sessions will convene at 8:30 a.m. on both days and will adjourn at 4:30 p.m. on April 8 and at 12 noon on April 9. The meeting is open to the public.

The purpose of the Committee is to advise the Department on its prosthetic programs designed to provide state-of-the-art prosthetics and the associated rehabilitation research, development, and evaluation of such technology. The Committee also advises the department on special disability programs which are defined as any program administered by the Secretary to serve veterans with spinal cord injury, blindness or vision impairment, loss of or loss of use of extremities, deafness or hearing impairment, or other serious incapacities in terms of daily life functions.

On the morning of April 8, the Committee will receive briefings by the Chief Consultant, Rehabilitation Strategic Healthcare Group, and the Director, Capital Asset Realignment for Enhanced Services (CARES) Program. In the afternoon, the Committee will be briefed by the directors of VA's special disability programs—spinal cord injury, blind rehabilitation, prosthetics, audiology and speech pathology. Additional briefing will be provided by the program directors of ophthalmology and optometry. On the morning of April 9, the Committee will be briefed by the Director of the Rehabilitation Research and Development Service and will review the most recent report on maintaining treatment capacity in VA's special disability programs.

No time will be allocated for receiving oral presentations from the public. However, members of the public may direct questions or submit written statements for review by the Committee in advance of the meeting to Ms. Cynthia Wade, Veterans Health Administration, Patient Care Services, Rehabilitation Strategic Healthcare Group (117), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Any member of the public wishing to attend the meeting should contact Ms. Wade at (202) 273–8485.

Dated: March 6, 2003.

**E. Phillip Riggin,**

*Committee Management Officer.*

[FR Doc. 03–6100 Filed 3–12–03; 8:45 am]

BILLING CODE 8320–01–M

## DEPARTMENT OF VETERANS AFFAIRS

### VA Fleet Alternative Fuel Vehicle (AFV) Program Report

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Energy Policy Act of 1992 (EPAct) (42 U.S.C. 13211–13219) as amended by the Energy Conservation Reauthorization Act of 1998 (Pub. L. 105–388), the Department of Veterans Affairs' annual alternative fuel reports are available on the following Department of Veterans Affairs Web site: *http://www.va.gov/afv*.

**FOR FURTHER INFORMATION CONTACT:** Elaine Jackson, (202) 273–5859.

Approved: March 3, 2003.

**Anthony J. Principi,**

*Secretary of Veterans Affairs.*

[FR Doc. 03–6098 Filed 3–12–03; 8:45 am]

BILLING CODE 8320–01–P

# Corrections

Federal Register

Vol. 68, No. 49

Thursday, March 13, 2003

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

## DEPARTMENT OF THE TREASURY

### 31 CFR Part 103

**RIN 1506–AA28**

### Financial Crimes Enforcement Network; Anti-Money Laundering Programs for Dealers in Precious Metals, Stones, or Jewels

*Correction*

In proposed rule document 03–4171 beginning on page 8480 in the issue of Friday, February 21, 2003 make the following correction:

**§103.140 [Corrected]**

On page 8486, in §103.140, in the first column, in paragraph (d), in the fifth line, '' May 22, 2003'' should read, ''[Insert date that is 90 days after the date on which the final regulation to which this notice of proposed rulemaking relates is published in the Federal Register]''.

[FR Doc. C3–4171 Filed 3–12–03; 8:45 am]

BILLING CODE 1505–01–D

## DEPARTMENT OF AGRICULTURE

### Forest Service

### 36 CFR Part 219

**RIN 0596–AB86**

### National Forest System Land and Resource Management Planning

*Correction*

In proposed rule document 03–5116 appearing on page 10420 in the issue of Wednesday, March 5, 2003, make the following correction:

On page 10420, in the second column, the subject heading is corrected to read as set forth above.

[FR Doc. C3–5116 Filed 3–12–03; 8:45 am]

BILLING CODE 1505–01–D

## DEPARTMENT OF THE TREASURY

### Financial Management Service

### Privacy Act of 1974; System of Records

*Correction*

In notice document 03–4457 beginning on page 8964 in the issue of Wednesday, February 26, 2003, make the following correction:

On page 8965, in the second column, in the sixth line from the bottom, the heading ''**TREASURY/FMS .015**'' should read, ''**TREASURY/FMS .016**''.

[FR Doc. C3–4457 Filed 3–12–03; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Thursday,
March 13, 2003

# Part II

# Department of Health and Human Services

## Food and Drug Administration

## 21 CFR Parts 111 and 112

## Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements; Proposed Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 111 and 112**

**[Docket No. 96N–0417]**

**RIN 0910–AB88**

# Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. 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. The provisions would require manufacturers to evaluate the identity, purity, quality, strength, and composition of their dietary ingredients and dietary supplements. The proposed rule is one of many actions related to dietary supplements that we (FDA) are taking to promote and protect the public health.

**DATES:** Submit written or electronic comments by June 11, 2003. Submit written or electronic comments on the collection of information by April 14, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Fax written comments on the information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Stuart Shapiro, Desk Officer for FDA, Fax (202) 395–6974, or electronically mail comments to *sshapiro@omb.eop.gov.*

**FOR FURTHER INFORMATION CONTACT:** Karen Strauss, Center for Food Safety and Applied Nutrition (HFS–821), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

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c. More restrictive CGMP regulations than the proposed regulations
d. HACCP without the other elements of CGMP regulations
e. Require final product testing only
f. Regulate only high-risk products
3. Coverage of the Proposed Rule
4. Baseline Practices
5. Baseline Risk
6. Benefits and Costs
a. Reduced illnesses
b. Fewer products recalled
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## I. Background

### *A. Dietary Supplement Health and Education Act (DSHEA)*

DSHEA (Pub. L. 103–417) was signed into law on October 25, 1994. DSHEA, among other things, amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 402(g) (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. Such regulations shall be modeled after CGMP regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of CGMP may be imposed unless such standard is included in a regulation issued after notice and opportunity for comment in accordance with 5 CFR chapter V.

Congress enacted DSHEA to ensure consumers' access to safe dietary supplements. In the findings accompanying DSHEA, Congress stated that improving the health status of U.S. citizens is a national priority and that the use of dietary supplements may help prevent chronic diseases and maintain good health (Ref. 1). If dietary supplements are adulterated because they contain contaminants (such as filth), because they do not contain the dietary ingredient they are represented to contain (for example, a product labeled as vitamin C that actually contains niacin), or because the amount of the dietary ingredient thought to provide a health benefit (for example, folic acid to reduce the risk of neural tube defects or calcium in an amount to reduce the risk of osteoporosis) is not actually present in the supplement, then the consumer may suffer harm or may not obtain the purported health benefit from their consumption. CGMP regulations for dietary ingredients and dietary supplements will help to ensure that the potential health benefits that Congress identified as the basis for DSHEA are obtained and that consumers receive the dietary ingredients that are stated on the product label.

DSHEA directed the President to appoint a Commission on Dietary Supplement Labels (the Commission) to consider several issues under DSHEA needing clarification. The Commission was to conduct a study on, and provide recommendations for, the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims. In making its recommendations, the Commission was to evaluate how best to provide truthful, scientifically valid, and nonmisleading information to consumers so that such consumers could make informed and appropriate health care choices for themselves and their families. The Commission's report (Ref. 80) states that the Commission supports the efforts of industry and FDA to develop appropriate CGMPs for dietary supplements. Guidance on the type of information that a responsible manufacturer should have to substantiate statements of nutritional support and safety is also included in the Commission's report. The Commission's report states that the substantiation files should include assurance that CGMPs were followed in the manufacture of the product.

### *B. The Advance Notice of Proposed Rulemaking*

On November 20, 1995, representatives of the dietary supplement industry submitted to FDA an outline for CGMP regulations for dietary supplements and dietary supplement ingredients. We evaluated the outline and determined that it provided a useful starting point for developing CGMP regulations. Nonetheless, we believed that the industry outline did not address certain issues that should be considered when developing a proposed rule on CGMPs for dietary ingredients and dietary supplements. For example, the industry outline did not address the need for specific controls for automatic, computer-controlled or assisted systems.

In addition to identifying a number of issues that were not included in the industry outline but on which we wanted public comment, we also recognized that other interested parties, such as consumers, other industry segments who had not participated in developing the outline, and the health care community should have an opportunity to provide comments on CGMPs for dietary supplements before we developed a proposal. Therefore, in the **Federal Register** of February 6, 1997 (62 FR 5700), we issued an advance notice of proposed rulemaking (ANPRM) asking for comments on whether to institute rulemaking to develop CGMP regulations for dietary ingredients and dietary supplements and what would constitute CGMP regulations for these products.

The ANPRM contained the entire text of the industry outline. We also asked nine questions (which we discuss later in section II.B of this document) in the ANPRM. The questions focused on issues that the industry outline did not address such as those issues noted above. We received approximately 100 letters in response to the ANPRM. Each of those letters contained one or more comments. The comments came from consumers, consumer advocacy groups, health care professionals, health care professional organizations, industry, and industry trade associations. The majority of comments responded both to the nine questions we asked in the ANPRM and on certain provisions in the industry outline. We also address the comments on the nine questions in section II.B of this document. We discuss significant comments about certain provisions in the industry outline in our discussion of related proposed requirements.

Included with its comments to the ANPRM, the United States Pharmacopeia (USP) submitted a copy of its general chapter, ''Manufacturing Practices for Nutritional Supplements,'' (Ref. 2) and in March/April 2002, USP proposed revisions to this general chapter to introduce provisions pertaining to botanical preparations (Ref. 82). In February 2000, we received a copy of the National Nutritional Foods Association's (NNFA) ''NNFA Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements'' (Ref. 3). We found that the industry outlines published in the ANPRM, the USP manufacturing practices, and the NNFA standards were useful in developing this proposed rule. We included certain provisions found in these outlines in this CGMP proposed rule. These three outlines indicate that dietary ingredient and dietary supplement manufacturers already recognize that there are basic, common steps needed to manufacture a dietary ingredient or dietary supplement that is not adulterated although, as established in the regulatory impact analysis, a large percentage of manufacturers do not follow a good manufacturing model. For example, these practices include requirements for:

- Designing and constructing physical plants that facilitate maintenance, cleaning, and proper

manufacturing operations or to prevent mixup between different raw materials and products;

- Establishing a quality control unit;
- Establishing and following written procedures for:

1. Maintaining and cleaning equipment and utensils;
2. Receiving, testing, or examining materials received and testing of finished product;
3. Using master and batch control records;
4. Handling consumer complaints; and
5. Maintaining records for laboratory tests, production control, distribution, and consumer complaints.

Based on the ANPRM, the comments that we received in response to the ANPRM, our outreach activities (which we discuss below), and our own knowledge and expertise about CGMPs for foods, drugs, cosmetics, devices, and biologics, we are proposing to establish these CGMP regulations for dietary ingredients and dietary supplements. The proposed regulations would impose requirements for: (1) Personnel, (2) physical plants, (3) equipment and utensils, (4) production and process controls, (5) holding and distributing, (6) consumer complaints related to good manufacturing practices, and (7) records and recordkeeping.

*C. Industry and Consumer Outreach*

During 1999, we conducted a number of outreach activities related to dietary supplements. We held several public meetings to obtain input from the public on developing 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 may have on small businesses. Additionally, FDA staff toured several dietary supplement manufacturing firms to better understand the manufacturing processes and practices that potentially would be subject to a CGMP regulation for dietary ingredients and dietary supplements. Each of these activities contributed to our knowledge about the industry.

1. Dietary Supplement Strategic Plan Meetings

We held public meetings on June 8 and July 20, 1999, to collect stakeholder comments on the development of our overall strategy for achieving effective regulation of dietary supplements. We designed the meetings to provide an opportunity for public comment on both the activities we should undertake as part of an overall strategy and the prioritization of those activities. In the notices for these meetings, we identified the development of CGMPs for dietary supplements as one activity that should be considered in an overall strategy.

During and after the strategic meetings, we received comments from consumers, consumer advocacy groups, health care professionals, health care professional organizations, industry, and industry trade associations. The comments addressed a wide range of activities related to regulating dietary supplements. (These comments can be seen at our Dockets Management Branch (*see* **ADDRESSES**) in docket number 99N–1174.) The comments generally identified the development of CGMP regulations as a high priority activity that should be included in any FDA strategic plan for regulating dietary supplements. Some comments that addressed the development of CGMPs are summarized as follows:

- It would be useful to industry to have FDA establish CGMPs especially for small and intermediate-size firms that are not clear on what they should be doing;
- CGMPs would establish a level playing field for industry, which would help prevent irresponsible firms from making and selling adulterated products;
- CGMPs should be able to accommodate a wide variety of firms, that is, small and large firms that manufacture a wide array of different types of products and ingredients;
- CGMPs should ensure that consumers get dietary supplements with the strength and the purity that consumers expect;
- CGMPs should ensure that every dietary supplement on the market has the safety, identity, purity, quality, and strength it purports in the label to possess;
- CGMPs should include ingredient identity testing and other testing;
- CGMPs should ensure that dietary supplements are produced using a master formula procedure and produced in a sanitary facility;
- CGMPs should require that manufacturers have documented evidence that their manufacturing process is under control on a consistent basis;
- CGMPs should require manufacturers to test dietary ingredients, particularly imported botanicals, for heavy metals, pesticides, and industrial contaminants;
- CGMPs should require expiration dating and testing for dissolution and bioequivalence;
- CGMPs should require that companies report adverse reactions; and
- CGMPs should include guidance on testing for ingredient identity and adulteration with toxic substances.

2. Small Business Outreach Meetings

We held public meetings on July 12, September 28, and October 21, 1999, to collect information from industry and others that would help us to understand the economic impact on small businesses of CGMP regulations for dietary supplements. Transcripts of these public meetings (docket number 96N–0417, ''Development of Strategy for Dietary Supplements'') are available at our Dockets Management Branch or electronically at *http://www.fda.gov/ohrms/dockets/dockets/96n0417/tr00001.pdf*. Public comments from small businesses included both support of and concern for CGMP regulations. Small businesses expressed concerns about the cost and the time involved in complying with any rule that contains the following requirements:

- Conducting tests to determine identity, purity, quality, strength, and composition of dietary ingredients and dietary supplements;
- Maintaining written procedures and records documenting that procedures are followed; and
- Providing data that support expiration dating.

Public comments from small business expressed support for dietary supplement CGMP regulation. Some small businesses (1 with 15 employees) commented that they have CGMPs in place with written procedures tailored to the size of their operations. One small business with sales under $1 million commented that their plant materials received in fresh form are identified onsite by a botanist, and when the onsite botanist is not able to confirm identity, the plant material is sent to an outside laboratory that conducts chemical analysis to confirm identity.

3. Site Visits to Dietary Supplement Manufacturing Firms

During the summer and fall of 1999, we visited eight dietary supplement manufacturing firms. These visits included firms that: (1) Manufacture a vitamin using a fermentation process; (2) grind, sift, blend, and otherwise treat raw agricultural commodities (*e.g.*, botanicals); (3) manufacture dietary ingredients for use in manufacturing dietary supplement tablets, capsules, softgels, and powders; (4) manufacture dietary supplements for packaging and labeling by others; and (5) manufacture, package, and label dietary supplements under their own and others' labels. The

firms varied in size and were located in several parts of the country.

We found an array of manufacturing, packaging, and holding practices in the firms. The practices included the following:

- Using CGMPs similar to those included in the ANPRM;
- Using automatic systems to quarantine, segregate, approve, and release inventory;
- Following written procedures;
- Having quality control units with the responsibility and authority outlined in the ANPRM;
- Performing one or more tests on dietary ingredients and dietary supplements to determine the identity, purity, quality, strength, and composition;
- Verifying the reliability of suppliers' certifications; and
- Documenting and maintaining records for certain procedures, such as master and batch production, quality control and laboratory operations, distribution, and processing consumer complaints.

*D. Food Advisory Committee Report*

In February 1998, the Food Advisory Committee (FAC) established a Dietary Supplement Working Group to consider what constitutes adequate testing for identity of different dietary ingredients and what records are necessary to demonstrate that CGMPs are maintained throughout the manufacturing and distribution process. The working group issued a report that discussed the selection of the most appropriate and reliable identity test and the general principles for consideration in setting performance standards for such tests (Ref. 4). The report also identified the types of records that would be necessary to demonstrate that CGMPs are maintained throughout the manufacturing and distribution process. On June 25, 1999, the working group presented its report, in draft form, during an FAC public meeting. We received public comments during and after the June 25, 1999, public meeting.

Although this proposal does not address dietary ingredient identity testing in the same detail as the working group's report, we considered the report in developing requirements for identity testing and CGMP records requirements in this proposal. The working group's report may be useful in developing industry guidance to supplement a CGMP regulation for dietary ingredients and dietary supplements. We discuss dietary ingredient and dietary supplement identity testing and recordkeeping for CGMP proposed requirements in more detail later in this document.

*E. FDA's Decision To Propose a Rule*

This proposed regulation, which sets forth proposed CGMPs for dietary ingredients and dietary supplements, is part of our overall strategy for regulating dietary supplements in a manner that promotes and protects the public health. Before drafting the proposal, FDA considered public comment in response to the ANPRM and to public meetings, observations at site visits to dietary supplement manufacturers, and advisory group reports. In drafting this proposal, FDA used, in part, the industry coalition outline that was published as an ANPRM (62 FR 5700) in which the industry adopted broad provisions beyond those found in part 110 (21 CFR part 110). FDA's purpose at this proposed rule stage is to present a broad enough scope so that it may receive comment on the depth and breadth of what should be considered by the agency in developing a final rule. Our intent is to provide the proper balance of regulation so that dietary ingredients and dietary supplements are manufactured in a manner to prevent adulteration using recognized scientific principles and both industry and consumer expectations that are reasonable and appropriate. Therefore, FDA seeks comment on whether each of the proposed provisions are necessary to ensure the safety and quality of dietary ingredients and dietary supplements and whether they are adequate to protect the public health. In addition, we seek comment on whether there are certain provisions that are not proposed but that may be necessary. Comments should include justification for why provisions may or may not be necessary, including supporting data where appropriate. If comments assert that certain provisions are not necessary, comments should include an explanation on how, in the absence of the requirement, one can ensure that there would be adequate protection of the public health when there is risk of adulteration. Comments also should address whether the gains to consumers in product safety and quality are warranted. Moreover, assuming that this proposal does advance the public health, comments should address whether there is any reason to apply different requirements, including greater or lesser requirements on small firms as compared to larger firms and the rationale for doing so. Finally, comments should address the agency's legal authority to issue these regulations.

In deciding whether to propose CGMP regulations for dietary supplements, we asked ourselves:

- Why Are CGMP regulations needed?
- How will CGMP regulations take into account technical feasibility? and
- How can FDA help industry achieve compliance with CGMPs?

1. Why Are CGMPs Needed?

CGMP regulations for dietary ingredients and dietary supplements are necessary to promote and protect the public health. In addition, CGMP regulations would benefit consumers economically and would benefit industry.

a. *CGMPs help protect the public health.* The dietary supplement industry is one of the fastest growing product areas that FDA regulates. In 1999, *Prevention* magazine conducted a survey entitled ''Consumer Use of Dietary Supplements'' (Ref. 5). The survey used data from telephone interviews with a nationally-representative sample of 2,000 adults living in households with telephones in the continental United States. The telephone interviews were done in April and May, 1999. Using population estimates based on the Census Bureau's March 1998 Current Population Survey Estimates, the survey stated that approximately 186,014,712 adults live in the households with telephones in the United States and that an estimated 158.1 million of these Americans in households with telephones use dietary supplement products. These consumers spend approximately $8.5 billion a year on dietary supplements. The survey also found that:

- Only 41 percent of the surveyed consumers who use vitamins and minerals think they are very safe and only 50 percent think they are somewhat safe;
- Only 24 percent of the surveyed consumers who use herbal products think they are very safe; and only 53 percent think they are somewhat safe; and
- Twelve percent of the surveyed consumers who have used dietary supplements say they have experienced side effects or adverse reactions from their use of dietary supplements.

The survey also found strong public support for increased Government regulation of dietary supplements; 74 percent of the surveyed consumers reported that they think that the Government should be more involved in ensuring that these products are safe and do what they claim to do.

However, unlike other major product areas, there are no FDA regulations that

are specific to dietary ingredients and dietary supplements that establish a minimum standard of practice for manufacturing, packaging, or holding. The absence of minimum standards has contributed to the adulteration and misbranding of dietary ingredients and dietary supplements by contaminants or because manufacturers do not set and meet specifications for their products, including specifications for identity, purity, quality, strength, and composition. Thus, CGMP regulations are necessary to protect the public health because a CGMP rule would establish a minimum standard of practice for manufacturing, packaging, and holding dietary ingredients and dietary supplements.

The following examples illustrate the wide range of dietary ingredient and dietary supplement adulteration caused by manufacturing, packaging, or holding practices. The examples, although not exhaustive, demonstrate why CGMPs are necessary to protect public health:

• In 1997, we received an adverse event report (AER) regarding a young woman who had taken a dietary supplement and experienced a life-threatening abnormal heart function (Ref. 6). We investigated the AER and determined that the dietary supplement the woman consumed contained *Digitalis lanata,* a plant that can cause life-threatening heart reactions (Refs. 6 through 10). We found *D. lanata* in samples of raw material labeled ''plantain'' that was a dietary ingredient in one of the dietary supplement products used by this woman (Ref. 6). A nationwide listing of manufacturers indicated that 183 firms may have used the contaminated dietary ingredient in dietary supplements. The proposed CGMP regulations, had they been in effect, would have required identity and purity tests of dietary ingredients and dietary supplements and would likely have prevented the use of the *D. lanata* in these dietary supplements.

• In 1998, the American Herbal Products Association (AHPA) surveyed its members about commonly adulterated botanicals and methods useful in detecting adulteration in botanicals (Ref. 11). AHPA members identified 43 botanicals, including *D. lanata* contaminated plantain, that are commonly adulterated with contaminants, the common adulterant for each botanical, and a method for identifying the adulterant. For example, aflatoxin and mycotoxin (toxic compounds produced by certain molds) are known to contaminate certain herbal and botanical dietary supplements (Refs. 11 through 14). Under this proposed rule, a manufacturer would have to establish specifications for botanicals that may contain toxic compounds and conduct testing to ensure that there are not toxic compounds present that may adulterate the dietary ingredient or dietary supplement.

• We have found manufacturers using nonfood-grade chemicals to manufacture dietary supplements (Ref. 15). The proposed rule would require that manufacturers establish specifications for components used in manufacturing and also would require manufacturers to establish and follow laboratory control procedures that include criteria for establishing appropriate specifications. The proposal would further require manufacturers to conduct testing to confirm that their specifications are met. These requirements, if finalized, would ensure that manufacturers establish and use appropriate criteria, such as using food-grade rather than industrial-grade chemicals, and would ensure that manufacturers conduct testing to confirm that food-grade chemicals were received from the supplier.

• Also during inspections, we have found insanitary conditions in physical plants where dietary ingredients or dietary supplements were manufactured, packaged, or held (Ref. 16). Pest infestation, building and equipment defects, and leaking pipes that drip onto dietary supplements are examples of insanitary conditions that we have found that may lead to product adulteration and could cause consumer illnesses and injuries. The proposed rule would require a manufacturer, packager, or holder to maintain its physical plant used for these activities in a sanitary condition.

• In the past, we have been involved in the recall of dietary supplements contaminated with lead (Ref. 17), salmonella (Ref. 18), *Klebsiella pneumonia* (Ref. 19), botulism (Ref. 20), and glass (Ref. 21). These contaminants can cause serious illness or injury and, in the case of lead, may result in chronic irreversible cognitive defects in children and progressive renal failure in adults. The proposed rule would require dietary ingredients and dietary supplements to be manufactured, packaged, and held in a manner that prevents adulteration, including adulteration by the contaminants such as those described.

• We also have been involved in recalls for super- and subpotent dietary supplements. Recalls of superpotent dietary supplements have included the following dietary ingredients: Vitamin A (Ref. 22), vitamin D (Ref. 23), vitamin B6 (Ref. 24), and selenium (Ref. 25). Each of these dietary supplements contained dietary ingredient levels that could have caused serious illness or injury. Illnesses or injuries such as nausea, vomiting, liver damage, and heart attack were reported from superpotent niacin at an average level of 452 milligrams (mg) niacin, well above the upper limit for adults of 45 mg daily (Ref. 26). Recalls for subpotent dietary supplements have included a recall of folic acid because the dietary supplement contained 34 percent of the declared level (Ref. 27). Such a product would be misbranded under section 403 of the act (21 U.S.C. 343). Folate plays a well-documented and important role in reducing the risk of neural tube defects. Neural tube birth defects, primarily spina bifida and anencephaly, cause serious lifetime debilitating injuries and disabilities, and even death. Thus, use of subpotent folic acid by women who are or may become pregnant may result in increased risk of having a child with a neural tube defect. The proposed rule would require manufacturers to establish specifications for the dietary supplement the manufacturer makes and then meet those specifications. Therefore, if the proposed rule is finalized, if the label for a folic acid supplement declares that the dietary supplement contains a certain level of folic acid, the folic acid supplement must actually contain that level, or we would consider the folic acid supplement to be adulterated under section 402(g) of the act.

• Other recalls have been necessary because of undeclared ingredients, including color additives (Refs. 28 and 29), lactose (Ref. 30), and sulfites (Ref. 31). Undeclared ingredients, such as color additives, lactose, and sulfites, may cause potentially dangerous reactions in susceptible persons (Ref. 32). The proposed rule would require manufacturers to verify that the correct labels have been applied to dietary ingredients and dietary supplements produced. The master manufacturing record would have to identify each ingredient required to be declared on the ingredient list under section 403 of the act.

• A study found that dietary ingredient content varied considerably from the declared content (Ref. 33). The study examined ephedra alkaloids in 20 herbal dietary supplements containing ephedra (Ma Huang) to determine their ephedra alkaloid content. This study found that norpseudoephedrine was often present in the ephedra dietary supplements. The study also observed significant lot-to-lot variations in alkaloid content for four products,

including one product that had lot-to-lot variations of ephedrine, pseudoephedrine, and methylephedride that exceeded 180 percent, 250 percent, and 1,000 percent, respectively. Half of the products tested differed in their label claims for ephedra alkaloid content and their actual alkaloid content. In some cases, the discrepancy exceeded 20 percent. One product did not have any ephedra alkaloids. Lot-to-lot variation in dietary ingredients is a public health problem particularly because conditions of use recommended or suggested in the labeling of dietary supplements are presumably based on the dietary supplement containing a certain amount of the dietary ingredient. If the dietary supplement contains more or less than the amount that the manufacturer represents, then the consumer does not receive the potential health benefit from the dietary supplement or is exposed to an amount that could present risk of injury or illness. The proposed rule would require manufacturers to establish controls, including master manufacturing and batch production records to ensure that they use the correct amount of the dietary ingredient to produce the dietary supplement, and that they apply the correct label to the dietary supplement.

- A private company analyzed a sample of dietary supplements and found that some dietary supplements did not contain the dietary ingredients claimed on the label (Ref. 34). The study found that 25 percent of gingko biloba products, 20 percent of saw palmetto, 33 percent of glucosamine, chrondroitin and combined glucosamine/chondroitin, and 50 percent of SAMe did not contain the dietary ingredients claimed in their product labels. The proposed rule would require manufacturers to establish and meet specifications for the identity, purity, quality, strength, and composition of dietary supplements.

Given the wide range of public health concerns presented by the manufacturing, packaging, and holding practices for dietary ingredients and dietary supplements, a comprehensive system of controls is necessary to prevent adulteration and misbranding. CGMPs are intended to establish such a comprehensive system. Manufacturers who operate in accordance with CGMPs would be less likely to distribute adulterated and misbranded dietary ingredients or dietary supplements than those who do not meet the requirements. Quality assurance will maximize the probability that unadulterated dietary supplements will reach the marketplace.

Establishing CGMP regulations for dietary supplements is only part of our broad science-based regulatory program for dietary supplements that is necessary to give consumers a high degree of confidence in the safety, composition, and labeling of dietary supplements. Aside from our CGMP efforts, we have taken other steps to protect the public health, such as:

- Reviewing claim notifications under section 403(r)(6) of the act to identify unlawful claims;
- Reviewing new dietary ingredient notifications to ensure that new dietary ingredients are reasonably expected to be safe under section 413 of the act (21 U.S.C. 350b);
- Evaluating the nutrition labeling of dietary supplements;
- Monitoring, through AERs voluntarily submitted to FDA, the occurrence of adverse events to identify potentially unsafe products; and
- Taking compliance actions against products that are adulterated or misbranded.

The CGMP regulation, if finalized, would, along with our other dietary ingredient and dietary supplement initiatives, contribute further to the protection of public health.

b. *CGMPs benefit consumers.* In addition to the public health benefits for consumers, CGMP regulations for dietary ingredients and dietary supplements will benefit consumers in other ways. Consumers should not have to wonder whether the dietary supplements they buy are adulterated or whether they contain the correct dietary ingredients or contain the dietary ingredients in the amount stated on the product's label. Consumers who purchase a product that does not contain the amount or strength listed on the label experience an economic loss because they are paying for something that they did not receive. CGMPs would require manufacturers to establish and meet specifications for identity, purity, quality, strength and composition of dietary supplements to help ensure that consumers buy dietary supplements that are not adulterated, contain the dietary ingredients declared on the product's label, and contain the amount or strength listed on the label. Therefore, CGMPs would benefit consumers.

2. How Will CGMP Regulations Take Into Account Technical Feasibility?

In developing this proposed rule, we were careful not to propose requirements that are not technically feasible to meet. In some areas where there has been scientific study but where the science is still evolving, the proposal recognizes the evolving state of the science, but would give you maximum flexibility in meeting the requirement. For example, there are tests available for identity, purity, quality, strength, and composition of certain dietary ingredients or dietary supplements. Because many tests for identity, purity, quality, strength, and composition of dietary ingredient or dietary supplements have not been officially validated, the proposal would permit tests using methods other than those that are officially validated. By using the term ''officially validated,'' we mean that the method is validated using an interlaboratory collaborative study by which a proposed method is validated by independent testing in separate laboratories under identical conditions (Ref. 35). An AOAC International (formerly the Association of Official Analytical Chemists) Official Method is an example of an officially validated method. We discuss test methods validation in more detail later in this document.

In areas where scientific study is still evolving, we did not propose specific requirements. For example, we did not propose requirements for dissolution, disintegration, bioavailability, or expiration dating. In those areas, it may be premature to propose a requirement at this time. In the preamble to this rule, we identify those areas where additional scientific study is necessary before we can propose a dietary supplement CGMP requirement. For example, we did not identify defect action levels (DALs) for dietary ingredients because there are not enough data available to identify an appropriate DAL for most dietary ingredients. Likewise, further study is needed for some dietary ingredients before dissolution, disintegration, bioavailability, expiration dating, or other quality standard requirements can be proposed.

3. How Can FDA Help Industry Achieve Compliance With CGMPs?

During small business outreach public meetings and in comments to the ANPRM, members of the dietary supplement industry told us that they would like our help in determining how to implement CGMP regulations for dietary ingredients and supplements. We have heard that issuing guidance documents and education and training would be helpful. We invite comment on the use of guidance documents, education, training, or other approaches and potential sources of education and training that you believe would assist industry efforts to implement the proposed CGMP regulations, if finalized as proposed.

*F. Proposal Highlights and Requests for Comments*

This proposed rule is intended to ensure that manufacturing practices will not result in an adulterated dietary supplement and that supplements are properly labeled. This proposed rule, if finalized as proposed, will give consumers greater confidence that the dietary supplements they choose to use will have the identity, strength, purity, quality, or composition claimed on the label. A manufacturer of a dietary ingredient or a dietary supplement cannot make claims that state or imply that the dietary ingredient or dietary supplement is safe and/or effective simply because it has been manufactured in compliance with current good manufacturing practice (CGMP) requirements. However, we believe that a voluntary labeling statement about the fact that a dietary ingredient or dietary supplement has been made in compliance with CGMP requirements might be made lawfully under the act, provided that such a statement is made in an appropriate context and with adequate disclaimers so that consumers fully understand it and are not misled by it. The proposed rule governing CGMP requirements for dietary supplements address manufacturing controls to ensure that dietary ingredients and dietary supplements are produced in a manner that will not adulterate or misbrand such products. Compliance with any final rule, based on the proposal, will not ensure that the dietary ingredient or dietary supplement itself is safe or effective. Thus, the agency believes that an unqualified statement saying simply ''produced in compliance with dietary supplement current good manufacturing practice requirements,'' without more, could well suggest that a product may be safe and effective or somehow superior to other dietary ingredient and dietary supplement products that are subject to the same CGMP requirements. Such a statement would likely be considered misleading by FDA under sections 403(a)(1) and 201(n) of the act. We believe however, that it might be possible to cure an unqualified statement by including language clarifying to consumers that all dietary ingredients and dietary supplements must be manufactured in compliance with CGMP requirements and that such compliance does not mean that the dietary ingredient or dietary supplement is safe or effective. As usual, the manufacturer would be responsible for ensuring that any such voluntary labeling statements on its dietary ingredient and dietary supplement products are truthful and not misleading. The agency would review the lawfulness of such statements under sections 403(a)(1) and 201(n) of the act.

We propose requirements for: (1) Personnel, (2) the physical plant environment, (3) equipment and utensils, (4) production and process controls, (5) holding and distributing, (6) consumer complaints related to CGMPs, and (7) records and recordkeeping. Key provisions of the proposed rule are highlighted below. We also seek comment on whether certain additional provisions should be included as requirements in a final rule.

Proposed ''personnel'' requirements would require that you have qualified employees and supervisors, to take measures to exclude any person from your operations who might be a source of microbial contamination, and to use hygienic practices to the extent necessary to protect against contamination.

Proposed ''physical plant'' requirements are intended to help prevent contamination from your physical plant environment. You would be required to design and construct your physical plant in a manner to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, and holding. You would be required to keep your physical plant in a clean and sanitary condition and in sufficient repair to prevent contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed ''equipment and utensils'' provisions would require that you use equipment and utensils that are of appropriate design, construction, and workmanship for their intended use and that you provide for adequate cleaning and maintenance. You would be required to maintain and calibrate your instruments and controls for accuracy and precision and to ensure that automatic, mechanical, and electronic equipment works as intended. You would also be required to maintain, clean, and sanitize, as necessary, all equipment utensils and contact surfaces that are used to manufacture, package, or hold dietary ingredients or dietary supplements.

Under the proposed ''production and process controls'' requirements, you would be required to establish and use a quality control unit in your manufacturing, packaging, and label operations. We propose requirements for establishing and using master manufacturing records and batch control records to ensure batch-to-batch consistency. Specifications would be required for any point, step, or stage in the manufacturing process where control is necessary to ensure that the dietary supplement contains the identity, purity, quality, strength, and composition claimed on the label. We propose flexible testing requirements: You would be required to test final products for adherence to specifications, unless a scientifically valid analytical method does not exist; in the latter case, you would be required to test incoming shipment lots of components, dietary ingredients, or dietary supplements for any such specification, and to test in-process for any such specification in accordance with the master manufacturing record where you determine control is necessary to ensure the identity, purity, quality, strength, and composition of the product.

Proposed ''holding and distributing'' requirements would protect components, dietary ingredients, dietary supplements, packaging, and labels against contamination and deterioration. You would be required to hold components, dietary ingredients, dietary supplements, packaging, and labels under appropriate conditions of temperature, humidity, and light so that their quality is not affected; and under conditions that do not lead to the mixup, contamination, or deterioration.

Proposed ''consumer complaints'' requirements would require that you keep a written record of each consumer complaint related to good manufacturing practices; review such complaints to determine whether the consumer complaint involves a possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any other requirements of this part, including those that may result in a possible risk of illness or injury (*i.e.*, an adverse event); and investigate a consumer complaint when there is a reasonable possibility of a relationship between the consumption of a dietary supplement and an adverse event. 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.

Proposed ''records and recordkeeping'' requirements would tell you how long you must keep certain records to show how you complied with the CGMP requirements. We would require that you keep written records for 3 years beyond the date of manufacture of the last batch of dietary ingredients

or dietary supplements associated with those records and have all required records, or copies of such records, readily available during the retention period for authorized inspection and copying by FDA when requested.

CGMP records document the manufacturer's operation throughout time and are essential to an enforceable regulation. Because FDA does not observe the manufacturer's operation fulltime, records can ensure that the FDA has the information needed to identify noncompliance and to bring a non-compliant manufacturer into compliance. Records can show that appropriate monitoring is performed, pinpoint with confidence when a deviation began and ended, and prove that required quality control measures and practices were performed as often as necessary to ensure control. Review of manufacturing records with sufficient frequency can ensure that any problems are uncovered promptly and can facilitate prompt modification, have an impact on the production of subsequent batches of the product, and prevent introduction of potentially hazardous dietary supplements into the market place. Review of consumer complaint records can facilitate the identification of trends in reports of illness or injury, identify related batch records to identify previously undetected manufacturing deviation, and have an impact on the prompt recall of any potentially hazardous dietary supplement.

We seek comment on whether the proposed recordkeeping requirements are not necessary to prevent adulteration; to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement; to an enforceable regulation; and for the other reasons cited. If comments assert that recordkeeping provisions are not necessary, comments should include an explanation of why recordkeeping requirements are not necessary including how, in the absence of the requirements, one can prevent adulteration, ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement, ensure an enforceable regulation, and the other reasons cited. If comments agree that the recordkeeping requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

Although records are not required in 21 CFR Part 110, CGMPs in manufacturing, packing, or holding human food, records are required in the other commodity-driven food CGMPs (*i.e.*, 21 CFR Part 129, Processing and bottling of bottled drinking water; 21 Part CFR 120, Hazard Analysis and Critical Control Point (HAACP) Procedures for the Safe and Sanitary Processing and Importing of Juice; 21 CFR Part 123, Fish and fishery products; 21 CFR Part 106 Infant formula quality control procedures; and 21 CFR Part 113, Thermally processed low-acid foods packaged in hermetically sealed containers). Further, records are included in the CGMPs submitted to FDA by industry, the National Nutritional Foods Association Standards, the NSF International draft standards (Ref. 83), and the USP draft Manufacturing Practices for Dietary Supplements.

We seek comment on whether certain additional provisions should be included as requirements in a final rule. For example, we invite comment on whether a final rule should include a requirement for certain personnel records; for written procedures in a number of areas; for equipment verification; and for expiration dating and related testing. Written procedures are included in the dietary supplement CGMP outline submitted to FDA by industry, National Nutritional Foods Association standards, the NSF International draft standards, and the USP draft Manufacturing Practices. In order to limit the burden to manufacturers, FDA is not proposing to require written procedures. However, FDA is proposing that manufacturers maintain appropriate records to ensure the identity, purity, quality, strength, and composition of a given product and records that are necessary for efficient enforcement and to permit trace back. Although we have not proposed requirements for written procedures as did these other groups, we seek comment on whether such practices should be included in a final rule. Later in this document, we request comments on specific written procedures and describe FDA's current thinking concerning what could be included in such a written procedure.

We also seek comment on whether this rule should include specific requirements for the use of animal-derived dietary ingredients, and requirements for persons who handle raw agricultural commodities. Specific requests for comment of this type are contained below in relevant sections of this preamble.

## II. General Issues

### *A. Legal Authority*

We are proposing these regulations under sections 201, 393, 409, 701(a), 704, and 801 of the act (21 U.S.C. 321, 903, 348, 371(a), 374, and 381) and sections 402 and 403 of the act and section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264).

Section 402(g) of the act gives us explicit authority to issue a rule regulating conditions for manufacturing, packaging, and holding 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.'' In addition, section 402(g)(2) of the act states that any 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 section 402(g)(2) of the act, which describes the general parameters of CGMPs for dietary supplements, Congress stated that the regulations were to be ''modeled after current good manufacturing practice regulations for food.'' To determine what Congress meant, we look to the plain meaning of the phrase. *Webster's II New Riverside University Dictionary* defines ''model'' as ''[a] preliminary pattern serving as the plan from which an item not yet constructed will be produced'' (Ref. 81). Thus, when Congress used the term ''modeled after'' Congress intended that we use the food CGMPs as a ''preliminary pattern'' for the dietary supplement CGMPs. If Congress had intended for the agency to adopt food CGMPs as the CGMPs for dietary supplements, Congress could have explicitly stated that dietary supplements were subject to food CGMPs.

The provisions in the dietary supplement CGMP proposal are modeled after food CGMPs. The general CGMP provisions for food in part 110 relate not only to insanitary production practices, but other practices, such as having appropriate quality control operations, to ensure that a food is manufactured in a manner that will not adulterate the food. Further, the CGMPs in part 110 describe the minimally acceptable practices for all food handling operations. They are not intended to cover specific issues that may relate to a particular product type, rather, are general provisions concerned with practices relating to the receiving, inspecting, quality control operations, packaging, segregating, processing, storing, and transporting of food. The specific provisions of the food CGMPs

are linked to hazards that are inherent to foods (*e.g.*, microbial contamination and contamination with macroscopic filth).

The proposed dietary supplement CGMPs are modeled after the food CGMPs in part 110 in that they cover the scope of practices related to the receiving, inspecting, quality control operations, packaging, segregating, processing, storing, and distribution of dietary ingredients and dietary supplements. Dietary supplements require many of the same types of sanitary practices and other practices as conventional food production in order to produce a product that is not adulterated; dietary supplements are subject to many of the same hazards as are conventional foods. However, dietary supplements have their own set of unique requirements as a result of the characteristics and hazards due to their ''hybrid'' nature, *e.g.*, dietary supplements can be considered as falling somewhere along the continuum between conventional foods on the one hand and drugs on the other. Thus, the CGMPs for dietary supplements need to address the characteristics and hazards of dietary supplements, the operations and processes used to manufacture dietary supplements, particularly those necessary to ensure the identity, purity, quality, strength, and composition claimed on the label.

Dietary supplements, unlike conventional foods, contain ingredients that are consumed in very small quantities, for example, in a tablet or capsule. Such ingredients may be intended to have an anticipated, specific physiological response. Such ingredients are more ''drug-like'' than ''food-like,'' in part, because very small changes in the strength, purity, or quality of the ingredient can have significant, and possibly adverse, health consequences to those who ingest it. Thus, the dietary supplement CGMPs, by necessity, need to include provisions related to identity, purity, strength, quality, and composition of the product so that the dietary supplement ''food'' product will be manufactured in a manner that will not result in adulteration.

Further, plant products that are used to produce dietary supplements may be ground or in a powder and not easily recognized compared to conventional food that is readily identifiable (*e.g.*, one can readily distinguish between white flour and white sugar, but not between ground plaintain and ground *D. lanata*). Thus, for the manufacturer to be sure that the dietary supplement contains the correct ingredient and the amount of the ingredient that is intended, the manufacturer must test or examine the ingredient using appropriate methods. The ''modeled after'' language in section 402(g) of the act provides the agency with the flexibility to devise CGMPs that make sense for dietary supplements, and that are based on the same principles as food CGMPs in part 110, *i.e.*, to prevent adulteration related to insanitary conditions or other conditions that may be necessary to prevent adulteration, given the nature of the specific food product and the characteristics of, and hazards inherent in, that food.

The scope of the legal authority for the proposed dietary supplement CGMPs includes the legal authorities upon which the food CGMPs are based. For example, section 402(a)(3) of the act states that a food is deemed adulterated if ''it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food.'' Section 402(a)(4) of the act states that a food is deemed adulterated if ''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.'' While section 402(a)(3) of the act focuses on the food itself, section 402(a)(4) of the act focuses on the conditions under which the food is prepared, packed, or held. Courts have adopted a broad reading of section 402(a)(4) of the act when we have taken actions to advance the public health (*see U.S.* v. *Nova Scotia Food Products Corp.,* 568 F. 2d 240, 248 (2d Cir. 1977)). The agency tentatively concludes that the authorities that it relied on for its umbrella CGMPs in part 110 for food are relevant to the authorities that it needs for this proposed rule for dietary supplement CGMPs. In addition, section 409 of the act is another provision that is relevant to dietary supplement CGMPs. Section 409 of the act addresses circumstances under which a food may be deemed adulterated based on the use of a food additive. Section 409 of the act is relevant to good manufacturing practices for foods, including dietary supplements, because a food would be deemed adulterated if it contained a food additive that was not used in a manner consistent with the statutory and regulatory requirements under section 409 of the act (*see* sections 402(a)(2)(C) and 409 of the act). Although Congress explicitly excluded ''dietary ingredients,'' as defined in section 201(ff) of the act, from the definition of food additive, (*see* section 201(s)(6) of the act), ingredients other than dietary ingredients in a dietary supplement are subject to regulation as a food additive under section 409 of the act, unless they are subject to an exception to the definition of ''food additive'' under section 201(s) of the act.

Moreover, dietary ingredients and dietary supplements may contain pathogenic bacteria or viruses that pose serious public health and safety concerns (Ref. 36). Botanical dietary ingredients are living plants that may contain different microorganisms. These include *Lactobacillus, Leuconostoc, Pseudomonas,* and *Xanthomonas* species and molds. Potential pathogens such as *Listeria monocytogens, Pseudomonas aeruginosa* and *Enterobacteriacae* may also be present. Secondary microbial contamination from soil (*Bacillus cereus, Clostridium perfringens* and mycotoxin-producing molds, *etc.*), animal feces (*Salmonella* and *Shigella* spp., *Escherichia coli*) and handling (*Staphylococcus aureus*) can also occur during harvesting, processing, and transportation (Ref. 36). Animal-derived dietary ingredients or dietary supplements may also pose a risk. For example, bovine colostrum, the lacteal secretion which precedes milk after a cow gives birth, is a substance that is used in dietary supplements and likely presents the same potential health risks as does milk. Bovine milk may contain pathogenic organisms capable of causing diseases in man such as tuberculosis or undulant fever. Glands and other animal tissues may contain the infective agent that causes transmissible spongiform encephalopathy (TSE) if they originate from an animal infected with the disease (Ref. 37).

We have authority to issue regulations under section 361 of the PHS Act. The Secretary delegated authority to the Commissioner of FDA (the Commissioner) to exercise the functions vested in the Secretary under section 361 of the PHS Act (see 21 CFR 5.10(a)(3)). This authority authorizes the Commissioner to issue and enforce regulations that, in the Commissioner's judgment, are necessary to prevent the introduction, transmission, or spread of communicable diseases from one State to another. Because this authority is designed to eliminate the introduction of diseases from one State to another, the Commissioner may exercise the authority over the disease-causing substance within the State where the food is manufactured, packaged, or held. The Commissioner, therefore, assumes the authority to issue regulations under the PHS Act to assure that foods are manufactured, packaged, and held under conditions that will prevent the introduction, transmission,

or spread of communicable diseases between States. Thus, the agency is invoking its authority under the PHS Act in this proposed rule to prevent the spread of communicable disease from dietary ingredients or dietary supplements in intrastate and interstate commerce.

In developing proposed CGMPs for dietary supplements, we relied on the basic concept underlying the food CGMPs and upheld by the courts. As a result, the basic concept for the food CGMPs and the proposed dietary supplement CGMPs is the same: To establish regulations that will help ensure that your practices for preparing, packaging, and holding dietary ingredients and dietary supplements do not result in an adulterated food entering interstate commerce.

In addition to relying on the broad authority in relevant sections of the act that we used to issue the food CGMP regulations, we look to the other relevant statutory language in section 402(g) of the act and the act as a whole in deciding the basis for our legal authority in proposing regulations related to the manufacture, packaging, and holding of dietary ingredients and dietary supplements. We note that certain terms Congress used in section 402(g)(2) of the act, *i.e.*, ''standards'' and ''current and generally available analytical methodology,'' show that Congress intended to give us the authority to establish regulations in this rule that do not have parallel provisions in other food CGMPs. Specifically, the second phrase of the second sentence in section 402(g)(2) of the act states that we ''may not impose standards for which there is no current and generally available analytical methodology.'' ''Standards'' and ''current and generally available analytical methodology'' are terms of art in the scientific field, and we are relying on the meaning of these terms in the field of science in these proposed CGMPs regulations, which implement that provision. This statutory language does not limit CGMPs for dietary supplements solely to the food CGMP regulations at the time DSHEA was enacted. If Congress had intended for the CGMPs for dietary supplements to be identical to the CGMPs for food, the language in section 402(g)(2) of the act relating to ''standards'' and ''current and generally available analytical methodolog[ies]'' would be meaningless. Thus, CGMP regulations for dietary ingredients and dietary supplements may include provisions relevant to dietary ingredients and dietary supplements that were not in current food regulations at the time DSHEA was enacted.

In addition to the broad authority in section 402(g) of the act, we look to the statutory scheme of DSHEA as a whole in proposing regulations related to the manufacture, packaging and holding of dietary ingredients and dietary supplements. Section 403(q)(5)(F) of the act (section 7(b) of DSHEA) requires that a dietary supplement product provide nutrition information. To comply with section 403(q)(5)(F) of the act, you must be able to identify the dietary ingredient or ingredients in a dietary supplement and the quantity of each. Moreover, the provisions in section 403(s) of the act relate to identity, purity, quality, strength, and compositional specifications of a dietary supplement. Thus, Congress sought to ensure in DSHEA that dietary supplements would provide accurate information to the consumer on the identity of the dietary ingredient and, if an herb or botanical, the source from which it is derived. Moreover, Congress sought to ensure that the dietary supplement would have the strength or meet the quality, purity, and compositional specifications that the dietary supplement is represented to meet. Because Congress established section 403(s) of the act—a provision that requires that a dietary supplement that bears representations about identity, purity, quality, strength, and compositional specifications meet those representations—it is reasonable for us to establish regulations for manufacturing, packaging, and holding addressing those same features. These representations relate to characteristics and hazards to which dietary supplements are subject. Further, in section 402(f) of the act, Congress identified circumstances under which a dietary supplement or a dietary ingredient would be deemed adulterated because it may present a significant or unreasonable risk of illness or injury. Congress expected that a dietary supplement would be manufactured in a way that ensures that the dietary supplement contains dietary ingredients that do not present an unreasonable risk of illness or injury and for which the conditions of use are based. Because one must be able to measure or analyze a dietary ingredient in order to determine whether a supplement in fact contains that dietary ingredient, it is reasonable for a proposed rule on CGMPs to include provisions related to identity, purity, quality, strength, and composition of a dietary ingredient or a dietary supplement. Moreover, it is reasonable to propose a requirement that records of complaints be kept and investigations be done, as necessary, so that the manufacturer and FDA can be aware of any potential problems relating to a particular dietary ingredient and these CGMPs, and so that a manufacturer can take appropriate action when necessary. The proposed CGMPs would reflect the act's regulatory scheme generally and, more specifically, DSHEA's provisions that contemplate consistent, controlled manufacture of dietary supplements (*see* sections 402(f) and 403(q)(5)(F) and (s) of the act). We tentatively conclude that, therefore, section 402(g)(2) of the act gives us the authority to develop dietary supplement CGMPs that are not identical to our food CGMPs and that are appropriately tailored to the manufacturing, packaging, and holding of dietary ingredients and dietary supplements.

Sections 701(a) and 704 of the act also give us authority to establish regulations related to CGMPs for dietary ingredients and dietary supplements. Under section 701(a) of the act, we have the authority to issue regulations for the efficient enforcement of the act, and such regulations have been held to have the force and effect of law (*see National Nutritional Foods Ass'n* v. *Weinberger,* 512 F.2d 688, 697–98 (2d Cir. 1975)). Section 704 of the act gives us the authority to inspect factories, warehouses, and other establishments in which foods, including dietary ingredients and dietary supplements, are manufactured, processed, packed, or held and to inspect their facilities, equipment, finished and unfinished materials, containers, and labeling.

In addition to having the authority to establish broad regulations for manufacturing, packaging, and holding dietary ingredients and dietary supplements, we also have the authority to require recordkeeping as part of these regulations. Two questions that we considered in deciding whether to propose requirements for recordkeeping included whether the statutory scheme as a whole justified the proposed regulation and whether the proposed recordkeeping requirements would be limited, would clearly assist in the efficient enforcement of the act, and would not create an unreasonable recordkeeping burden. In the other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are limited to what are necessary for the efficient enforcement of the act, and because the requests are limited, would therefore not create an unreasonable recordkeeping burden.

For this proposed CGMP rule for dietary ingredients and dietary supplements, recordkeeping is necessary to provide the type of

documentation that would demonstrate that dietary ingredients and dietary supplements are manufactured, packaged, and held under the conditions that would be required under the proposed CGMP regulations. Further, FDA is using its authority under sections 801 and 701(a) of the act in proposing recordkeeping requirements for dietary ingredients and dietary supplements that may not be marketed or sold in the United States and that are exported under section 801(e) of the act.

In addition to having the authority under the act to require recordkeeping, we also have authority to require access to the records. Because the practices set forth in the proposed CGMP rule are necessary to providing consumers with dietary supplements that are not adulterated, access to records that demonstrate that firms follow CGMPs is essential to confirming systematic compliance with CGMPs. We also have the authority to copy the records when necessary. We may consider it necessary to copy records when, for example, our investigator may need assistance in reviewing a certain record from relevant experts in headquarters. If we were unable to copy the records, we would have to rely solely on our inspector's notes and reports when drawing conclusions. A failure to have a required record would mean that a food is adulterated under section 402(g) of the act.

Recordkeeping will not only help the agency to determine whether dietary ingredients or dietary supplements were manufactured, packaged, and held consistent with CGMP regulations, but also will provide a public health benefit to consumers. When manufacturers keep records, for example, of lot or batch numbers, the records facilitate a manufacturer's recall of suspect products in case a recall becomes necessary. This benefits consumers because the manufacturer can recall its products that may be adulterated or misbranded more quickly.

*B. Issues From the ANPRM*

As stated previously, in addition to inviting comment on the industry-drafted CGMP outline, we asked nine questions in the ANPRM on CGMP issues for dietary supplements that the industry outline did not address. In this section, we summarize each question and the principal comments we received, and we respond to the comments. We address other significant comments about the ANPRM, other than the nine questions we asked, elsewhere in this document.

The nine questions in the ANPRM, comments, and our responses are as follows:

*Question 1.* Is there a need to develop specific defect action levels (DALs) for dietary ingredients?

The ANPRM stated that the use of a botanical in a dietary supplement may result in a much greater exposure to the botanical ingredient for consumers because the dietary supplement will be consumed in greater amounts than if the ingredient was in a food as a spice or flavoring agent.

Several comments stated that establishing DALs for dietary ingredients that are different than DALs for food is not necessary. The comments disagreed with our statement that dietary ingredients in dietary supplements and conventional foods are consumed in different quantities. For example, the comments stated that generally botanical ingredients are present in dietary supplements in approximately the same amounts normally consumed in conventional foods.

Other comments generally opposed applying the current DALs for foods to dietary ingredients and instead supported the development of DALs for dietary ingredients, especially for botanicals and herbals. Many comments recommended that we cooperate with industry, outside the rulemaking process, to develop DALs for dietary ingredients.

We disagree with the comments that state that establishing DALs for dietary ingredients that are different than DALs for food is not necessary because an ingredient in food and in a dietary supplement would be consumed in the same amounts. The comment did not provide evidence or examples to support the comment. Some food ingredients for which DALs have been established also are dietary ingredients used in dietary supplements. For example, a DAL has been established for whole ginger used in a conventional food. Ginger is also a dietary ingredient used in dietary supplements. We have found dietary supplements that recommend a daily intake of ginger of 4,815 mg, 1,260 mg, and 2,200 mg (Ref. 38). One teaspoon of raw ginger root is equal to 2,000 mg (2 grams (g)) and one teaspoon of ground ginger is equal to 1,800 mg of ginger (1.8 g) (Ref. 39). A recipe for gingersnaps yielding 18 cookies specifies 1 teaspoon ginger (Ref. 40). Thus, ginger would be consumed in greater amounts as a dietary supplement than as an ingredient in a conventional food. However, we have tentatively concluded that we do not have sufficient information to determine whether a DAL for a dietary ingredient should be established at a different level than what has been established for the same ingredient used in conventional food.

DALs are established for a food ingredient on a per weight basis. The DALs for whole ginger for ''insect filth and/or mold'' is an ''average of 3 percent or more pieces by weight are insect-infected and/or moldy'' and for ''mammalian excreta'' is an ''average of 3 mg or more of mammalian excreta per pound'' (Ref. 41). Because the DAL is established by weight of the whole ginger, the DAL for ginger would apply whether it is used as an ingredient in a conventional food or a dietary ingredient in a dietary supplement. Therefore, if we have established a DAL in the industry compliance document for a conventional food ingredient, that DAL also would apply to that ingredient when used as a dietary ingredient in a dietary supplement until such time that we would establish a different DAL for its use as a dietary ingredient (Ref. 41). However, we do not have many dietary ingredients that are included in the DAL compliance guide. We agree that DALs may be needed for some dietary ingredients, especially ingredients like botanicals that are subject to the same type of defects (such as mold and insect parts) as other food for which DALs have been established. We base DALs on scientific information such as literature surveys, scientific market surveys, and laboratory analyses and also on information gained through physical plant inspections. If and when we determine that we have sufficient information to develop DALs for dietary ingredients, we will consider whether to do so.

*Question 2.* We requested comments on appropriate testing requirements to provide positive identification of dietary ingredients, particularly plant materials, used in dietary supplements.

The ANPRM explained that the misidentification of dietary ingredients, particularly plant materials, used in dietary supplements may present a significant public health and economic concern. The ANPRM also noted that the analytical methodology available for identifying many dietary ingredients is limited. We invited comments on the technical and scientific feasibility of identifying different types of dietary ingredients. We also solicited information on what constitutes ''adequate testing'' for identity of different types of dietary ingredients, and, in the absence of testing, what types of practices would be effective alternatives to testing to ensure the

identity of different types of dietary ingredients.

Comments generally supported requiring tests of some kind to positively identify dietary ingredients and to verify dietary ingredient identity. The comments put forth different reasons, which ranged from ensuring public safety to preventing economic adulteration. Some comments suggested that suppliers should be responsible for identifying the dietary ingredients they supply to manufacturers and that manufacturers should be responsible for only verifying the identity of the finished product. Other comments stated that the manufacturer should be responsible for identification and should not rely on a supplier's certification.

Some comments raised issues relating to the actual identity tests that should be recommended or required and discussed analytical method selection and method options, use of and availability of official validated analytical methods, and certification of testing facilities that conduct identity tests on natural products. Some comments suggested that identity test method options should include organoleptic and microscopic methods and chemical analytical methods. The comments noted that selecting the appropriate method is dependent on the type and form of the ingredient. Other comments said that manufacturers should be responsible for selecting the appropriate method to confirm ingredient identity. Most comments recommended that we provide guidance to industry in defining what comprises adequate testing for different types of ingredients, but did not support regulations prescribing the test method or methods for specific ingredients.

Comments generally supported the use of a standard compendial method, such as those published by the USP or AOAC International. Where no published method exists, the comments suggested that manufacturers should be responsible for developing adequate and effective identification testing procedures, requirements, or practices to ensure the identity of the dietary ingredients they use. One comment from a vitamin manufacturer noted that most of its products have recognized and established identity tests as part of their compendial status. Other comments from botanical dietary supplement manufacturers noted that their current methods for identifying plant material are adequate, but that they will, over time, be enhanced by the availability of more widely recognized methods and techniques as a result of current work in this field. The comments noted that test methods that are presently available and used for identifying botanicals are not officially validated. If an officially validated method is not available for a dietary ingredient, several comments suggested working towards AOAC International validation and, in the interim, instituting peer review of less formal test methods. Other comments noted that the dietary supplement industry has begun an effort to develop validated test methods for several botanical ingredients. One comment suggested that it is important to develop methods that are subject to peer review and to institute a certification program for testing facilities because the analysis of natural products requires specialized training in natural product chemistry. The comment did not indicate who (*e.g.*, FDA or another organization) should develop a certification program.

Some comments only addressed identity testing of unprocessed botanicals. These comments said that for unprocessed botanicals in whole or in part (*e.g.*, flowers, roots, leaves, etc.), organoleptic techniques are sufficient provided that accurate records are maintained and that the manufacturing process provides a paper trail of positive identification. One comment suggested that a ''voucher specimen'' (a sample of the plant material) from the supplier along with a certificate of botanical identity would be an adequate record. The certificate of botanical identity would follow the material through the manufacturing process, thus creating a paper trail. The voucher specimen would be held for a specific period of time or, if necessary, serve as a permanent record.

Dietary ingredient identification is an important part of CGMPs. We agree with the comments that identity testing requirements are needed but that no single approach or test method may be appropriate for every dietary ingredient. For example, microscopic or organoleptic tests might be appropriate for herbs or plant parts (because you can see, taste, or smell them), but not appropriate for amino acids (which cannot be identified by the naked eye or identified by using your senses). A microscopic test might be appropriate for herbs that still have their leaves or other distinguishing marks or characteristics, but not for ground-up herbs. Thus, we agree with the comments stating that the key principle in dietary ingredient identification testing is to establish an appropriate procedure that will identify, with certainty, the dietary ingredients used in making a dietary supplement. We agree that a guidance document on ingredient identity testing may be useful, and we will consider future development of ingredient identity testing guidance documents.

Manufacturers should be responsible for identifying the ingredients that they use in their products and, in addition, for verifying that the dietary ingredients or dietary supplements they make contain the identity, purity, quality, strength, and composition that the manufacturer intends the product to have. As discussed previously in this document, we have found serious adverse events to be related to dietary ingredient misidentification. The manufacturer must conduct identity tests to ensure that they used the correct ingredient to prevent potential serious adverse events. We discuss identity testing for dietary ingredients and dietary supplements later in this document.

We agree with the comments that certification of testing facilities could be an important step in ensuring analytical quality. However, certification of testing facilities is outside the scope of this rule.

*Question 3.* FDA requested comments on standards that should be met in certifying that a dietary ingredient or dietary supplement is not contaminated with filth; that it is free of harmful contaminants, pesticide residues, or other impurities; that it is microbiologically safe; and that it meets specified quality and identity standards.

The ANPRM noted that, under § 110.80, a food manufacturer may accept a supplier's certification that its products do not contain microorganisms, filth, or other foreign material that would adulterate the product instead of testing or evaluating the supplier's products itself. As a result, we asked for comments on whether a certification will provide assurance that dietary ingredients are not contaminated or whether specific testing requirements are necessary.

Comments generally supported relying on a supplier's certification that a dietary ingredient is what it purports to be and is not contaminated. The comments stated that reliance on the supplier's certification should be an alternative to testing raw materials to detect microorganisms, filth, or foreign material so long as the reliability of the supplier's certification is confirmed. Most comments stated that manufacturers are responsible for determining, on a case-by-case basis, whether a supplier's certification provides adequate assurance that a dietary ingredient is what it purports to be and is not adulterated. Some comments based their support for

relying on a supplier's certification on § 110.80(a)(2) through (a)(4); these provisions allow food manufacturers to rely on a supplier's guarantee or certification that raw materials or other ingredients do not contain levels of microorganisms or toxins that may produce illness or are otherwise contaminated. The comments suggested various means for determining the reliability of a supplier's certification, including independent analysis, in-house testing, and review of protocols.

Other comments stated that, because the CGMP regulations in part 110 permit reliance on a supplier's certification and because section 402(g)(2) of the act specifies that the CGMP regulations for dietary supplements should be modeled after the CGMP regulations for food, a supplier's certification for dietary supplements must be acceptable.

We have considered the comments on whether a supplier's certification could provide adequate assurance that a dietary ingredient is what it purports to be and is not adulterated. We disagree that manufacturers may rely on such certifications to determine that an ingredient is not contaminated, for example, with filth or microorganisms. Using a supplier certification, guarantee, or certification in lieu of performing testing on each shipment lot of components, dietary ingredients, or dietary supplements is not appropriate because a supplier's certification or guarantee would not necessarily ensure that the identity, purity, quality, strength, or composition of a component, dietary ingredient or dietary supplement is met. We discuss testing requirements and why we believe that the use of supplier's guarantee or certification is not sufficient in lieu of a manufacturer's own testing in more detail later in this document.

*Question 4.* We asked for comments on whether a CGMP rule should require manufacturers to establish procedures to document, on a continuing or daily basis, that they followed preestablished procedures for making dietary supplements.

The ANPRM noted that the food CGMP regulations under part 110 do not require manufacturers to document that they are following established procedures prescribed for manufacturing a food. However, the ANPRM also noted that section 402(g) of the act does not preclude us from adopting CGMP requirements for dietary ingredients and dietary supplements that have no counterpart in part 110 if we have an appropriate basis for doing so.

Most comments generally supported requiring manufacturers to develop and follow written procedures and noted that the industry outline in the ANPRM would require written procedures for many processes and functions. Some comments noted that written procedures and day-to-day records documenting that the procedures were followed will ensure that products are safely and properly manufactured on a day-to-day basis and that this can be confirmed by periodic independent internal audits. One comment stated that the manufacturer should be responsible for ensuring, through employee training, self-audit programs, and batch records, that quality control and other procedures prescribed for the manufacture of a dietary supplement are properly and diligently executed. Other comments stated that it is good business practice to ensure product quality through periodic review of records and quality control audits and that failure to establish procedures will result in product recalls, potential injury, and litigation for damages for defective goods.

Some comments objected to any requirement for written procedures or documentation that the procedures were followed. The comments stated that section 402(g)(2) of the act states that dietary supplement CGMPs must be modeled after the food CGMP regulations and the food CGMP regulations do not require written procedures or documentation that procedures were followed.

We agree with those comments that support the development and use of written procedures by manufacturers and are considering whether we should require written procedures in a final rule. We are proposing requirements for documenting certain operations and processes while not requiring written procedures to remove underlying costs for establishing and updating such written procedures while preserving the records necessary to permit trace back. When manufacturers develop and follow written procedures such procedures help to ensure that manufacturers produce a consistent dietary ingredient or dietary supplement that is of a predictable quality and that is not adulterated. Following written procedures and documenting compliance with those procedures will ensure regular performance of a firm's established programs and procedures and will provide additional assurance of effective communication of appropriate information from the firm management to the line personnel. We invite comment on whether written procedures should be required in a final rule, and whether there are other procedures, that we should include in a final rule. We discuss written procedures for various stages of manufacturing, packaging, labeling, holding, and for handling consumer complaints later in this document.

We disagree, however, that records are not necessary to show that certain operations and processes are being performed. Records document that quality control operations and processes such as calibrating instruments and controls; manufacturing a dietary ingredient or dietary supplement batch; and handling consumer complaints were performed. We further discuss the basis for the proposed recordkeeping requirement for certain operations and processes later in this document. We believe that section 402(g) of the act allows us to require written procedures and documentation that the procedures were followed. As explained previously, such records may be necessary for ensuring that dietary ingredients and dietary supplements are manufactured, packaged, and held consistent with these regulations. Moreover, we believe that the fact that the food CGMPs in part 110 do not have recordkeeping requirements does not preclude us from proposing recordkeeping requirements in this proposed rule, although we seek further comment on the issue.

*Question 5.* We invited comment on whether dietary supplement CGMP regulations should require that firms have competent medical authorities evaluate reports of injuries or illnesses and to determine if followup action is necessary to protect the public health.

The ANPRM explained that many dietary supplements contain pharmacologically active substances, which distinguish dietary supplements from many foods, and some dietary supplements may contain potential allergens. Because the characteristics may result in adverse events in certain consumers, we asked whether we should consider requiring firms to take certain actions with respect to reviewing AERs. We also sought comments on whether a CGMP rule should require firms to establish procedures for determining whether a reported injury constitutes a serious problem, and what actions are to be taken when serious problems are identified.

Comments generally opposed requiring manufacturers to establish a procedure for evaluation and followup of reports of illness and injuries. Comments also opposed requiring that a competent medical authority evaluate all reports of illness or injuries to determine if followup action is necessary to protect the public health. Some comments, opposing requiring written procedures and evaluation,

suggested alternatives to requirements, such as using the Centers for Disease Control and Prevention, poison control centers, FDA's MedWatch program, and consumer complaint files to monitor and record injuries and illnesses attributed to marketed products.

In contrast, several comments supported a requirement for written procedures or medical evaluation of serious adverse events. Some comments stated that an evaluation procedure is necessary and that manufacturers are and should be responsible for establishing procedures to respond appropriately to reports of serious illness and injury that may have resulted from using a dietary supplement. Other comments stated that medical evaluations are not necessary because manufacturers should be using appropriate internal quality control procedures within their quality control units or elsewhere to identify the cause of adverse events and respond appropriately.

We agree with those comments stating that manufacturers are and should be responsible for evaluating consumer complaints. Manufacturers have an obligation to ensure that the dietary supplements that they put on the market are not adulterated or misbranded. Consumer complaints about a dietary supplement might indicate a CGMP-related problem associated with a dietary supplement. For example, a consumer complaint might identify a previously unknown manufacturing deviation that caused a batch of dietary supplements to be adulterated. Thus, a procedure for reviewing and investigating consumer complaints is recommended. Records of consumer complaints related to CGMPs, and the review and investigation of such records, are necessary and we discuss such a record requirement later in this document. In that discussion, we address what we mean by a consumer complaint and we address the comments on the type of evaluation that would be necessary for consumer complaints and whether the comments' suggested alternatives to written procedures and medical evaluations are sufficient to identify potential concerns.

Some comments objected to written procedures and medical evaluation arguing that such requirements go beyond the CGMP regulations for food and, therefore, would be contrary to section 402(g)(2) of the act. Other comments claimed that written procedures would present unwarranted potential criminal liability, that there are many unsubstantiated injuries and illness inherent in the food industry, and that dietary supplement safety problems are rare. These comments also stated that a costly and burdensome safety surveillance system is not warranted for these products, that the term ''serious adverse event'' is ambiguous, and that most manufacturers lack trained medical personnel to serve this function.

Because we have found dietary supplement problems that could have been prevented by CGMPs and that resulted in product recalls, we find that manufacturers must be able to identify these types of problems with their products. It is a manufacturer's responsibility to do so. We disagree with those comments stating that we do not have legal authority to require a manufacturer to evaluate consumer complaints as we propose to define that term in this proposed rule.

We also disagree that written procedures would present unwarranted potential criminal liability. Persons subject to regulation under the act and its implementing regulations may face civil or criminal action if they fail to comply with the act or our regulations (*see, e.g.*, sections 301, 302, and 303 (21 U.S.C. 331, 332, and 333) of the act). The fact that such an outcome is possible under the statutory scheme does not mean that a provision that would require written procedures and evaluation of consumer complaints is ''unwarranted.'' If we were to accept such a claim, then we would find it difficult to issue any regulation to implement the act, and that result would conflict with our obligation to protect the public health. Therefore, we reject the comments' argument regarding potential criminal liability and its effect on rulemaking.

We also disagree with the claim that there is no basis for requiring an evaluation of adverse events because there are many unsubstantiated reports of injuries or illness and because dietary supplement safety problems are rare. In the past, voluntary reports of injury or illness have identified adulterated dietary supplements. Consumer complaint reports associated with the use of marketed dietary supplements, such as *D. lanata* contaminated plantain, identified the need for further investigation and led to recalls or warnings to protect the public health (Ref. 6). Evaluation of consumer complaint reports can reveal patterns of adverse events that assist us and manufacturers in identifying the need for further investigation to determine what public health actions are needed.

For example, assume that, after you investigate an AER, you find that the product contained an ingredient that should not have been used and that the ingredient caused the adverse event. The fact that the wrong ingredient appeared in your product would indicate that some type of problem occurred in your manufacturing process of that product. Once you identify the ingredient as the cause of the problem, you would be able to take steps to remove any such product from the market and prevent the problem from recurring, helping to ensure product quality and purity, and restore consumer confidence that your products contain the correct ingredients. In short, investigations of consumer complaints benefit both manufacturers and consumers and these benefits will exist regardless of whether there are many or few injuries or illnesses believed to be associated with your product.

*Question 6.* We invited comment on whether a CGMP regulation for dietary supplements should require manufacturers to establish procedures to identify, evaluate, and respond to potential safety concerns with dietary ingredients. We asked whether such an evaluation is necessary, and, if so, what elements need to be included in such an evaluation and their relative importance (*e.g.*, the presence and potency of pharmacologically active substances, the presence of different microorganisms, the presence of different contaminants and impurities). We also asked whether we should require that these evaluations be documented in a firm's records, and, if so, what type of records would be adequate to document that such an evaluation had occurred.

In general, the comments opposed requiring manufacturers to establish procedures to identify, evaluate, and respond to potential safety concerns with dietary ingredients. Most comments claimed that such procedures are unnecessary because dietary ingredients have a history of safe use in food and that DSHEA is based on this history of prior use in food. Other comments argued that, because DSHEA is based on a history of prior use of existing dietary supplements and established a notification procedure for new dietary ingredients, a requirement concerning potential safety concerns for dietary ingredients would be beyond the scope of this rulemaking.

Several comments noted that for those dietary ingredients that do not have a history of safe use in food and are considered ''new dietary ingredients,'' as defined in section 413(c) of the act, DSHEA established procedures for evaluating safety concerns. Section 413(a)(2) of the act requires a manufacturer to submit a ''new dietary ingredient'' notification to FDA 75 days

before introducing or delivering a dietary supplement containing a new dietary ingredient into interstate commerce. The notification must provide the basis upon which the petitioner has concluded that the dietary supplement containing the new dietary ingredient is reasonably expected to be safe. Therefore, the comments argued that procedures to identify, evaluate, and respond to potential safety concerns are not necessary in a CGMP rule.

Other comments stated that FDA should not require procedures to identify, evaluate, and consider potential safety concerns with dietary ingredients because manufacturers already have an essential and critical responsibility to substantiate the safety of the dietary ingredients they use in manufacturing a product. The comments suggested that FDA does not need to require written procedures because manufacturers must consult the generally known and generally available scientific literature to determine that a dietary ingredient is safe. Some comments suggested that, instead of FDA requiring safety evaluations, a third-party could evaluate safety concerns. Several comments suggested that manufacturers who use dietary ingredients that have little history of use in food in the United States should retain documentation concerning the dietary ingredient's safety. One comment suggested that we issue a guidance document to identify the types of acceptable ''history of use'' standards for dietary ingredients having little history of use in food in the United States and to describe the documentation that would be needed regarding a dietary ingredient's safety.

Although the comments focused on the safety of using particular dietary ingredients, the safety concerns described in question 6 actually consist of two concepts: (1) Is the product formulated using safe dietary ingredients; and (2) is the product manufactured, packaged, and held in a manner that would not adulterate or misbrand the product? The proposed rule focuses on safety concerns related to the latter concept. Specifically, the proposed rule focuses on the steps and processes used in the manufacturing, packaging, and holding of the product to ensure, for example, that the product has the identity, purity, quality, strength, and composition claimed and does not become adulterated or misbranded. The agency notes that no comments appeared to argue that safety issues relating to potential contamination or adulteration related to manufacturing processes are outside CGMPs. As the comments recognize, manufacturers have an essential and critical responsibility to substantiate the safety of the dietary ingredients they use in manufacturing a product.

Section 402(g) of the act is not the only provision relevant to whether a dietary ingredient or dietary supplement may be deemed to be adulterated. Section 402(f)(1) of the act, in part, declares a dietary supplement to be adulterated if it:

- Presents a significant or unreasonable risk of illness or injury under conditions of use described in the labeling or, if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;
- Is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the dietary ingredient does not present a significant or unreasonable risk of illness or injury; or
- Is or contains a dietary ingredient that renders it adulterated under section 402(a)(1) of the act under the conditions of use recommended or suggested in the labeling. (Section 402(a)(1) of the act declares a food to be adulterated if it contains substances that are poisonous or deleterious substance that may render it injurious to health.)

Additionally, section 301(a) of the act prohibits the introduction of adulterated food into interstate commerce.

So, for a dietary ingredient or dietary supplement manufacturer to comply with sections 301(a) and 402(f)(1) of the act, it must take steps regarding potential safety concerns before it markets the product. Otherwise, if the manufacturer had no obligation to evaluate possible safety concerns before marketing a product, sections 301(a) and 402(f)(1) of the act would not make sense and the manufacturer would be acting contrary to the basic congressional intent behind DSHEA, which was to ensure that safe dietary supplements are available to consumers. For example, assume that a manufacturer wanted to market a new dietary ingredient but lacked evidence to show that it is safe. Under section 402(f)(1)(B) of the act, the manufacturer must have adequate information to provide reasonable assurance of the dietary ingredient's safety before it markets the dietary ingredient; otherwise, the dietary ingredient is adulterated under section 402(f)(1)(B) of the act, and section 301(a) of the act would prohibit its sale in interstate commerce. Thus, the manufacturer has a statutory obligation to examine safety concerns relating to the dietary ingredients it uses before it markets the product.

The proposed CGMP rule focuses on ensuring that the manufacturer knows what it is putting in its product and is manufacturing, packaging, and holding the product in a manner that will not adulterate or misbrand the product. For example, assume that you use a particular herb as your dietary ingredient. However, there are different species of that herb. Some species are poisonous; others are not. Additionally, there are variations within the same species of herb depending on where the herbs were grown. Some variants may contain higher levels of a particular dietary ingredient or marker compound than other variants. So, how do you know whether you have the right herb (nonpoisonous species of herb intended for use) and whether it meets your specifications? CGMPs would require that you check the identity of the herbs you receive; by doing so, you would be able to tell whether you have the correct herbs, whether your herbs are poisonous, or whether they meet your specifications. In this example, the potential safety concerns involve the dietary ingredient itself rather than any issue concerning contamination which would adulterate or may lead to adulteration of the dietary ingredient, and thus, the dietary supplement which contains the dietary ingredient.

As for the comments' arguments concerning a dietary ingredient's history of use, we do not need to address history of use as part of this CGMP proposal. CGMPs focus on how a product is made under current manufacturing processes. A dietary ingredient's history of use does not provide any assurance that a particular product has the identity, purity, quality, strength, and composition that it purports to have. Further, history of use does not necessarily provide any assurance that a particular product would not pose a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling or under ordinary conditions of use.

As for those comments discussing whether manufacturers or other parties should evaluate potential safety concerns, the proposed rule would require a manufacturer to evaluate a consumer complaint to determine whether the complaint relates to good manufacturing practices. Such an evaluation would include possible hazards to health resulting from the manufacturing, packaging, or holding of a product. Nevertheless, you should note that, insofar as compliance with the act and any CGMP regulations are

concerned, persons who market dietary ingredients and dietary supplements always remain responsible for their products. If the manufacturer markets the product, it would have to meet all proposed CGMP requirements, if the agency finalizes the rule as proposed. If another person buys a product (such as bulk dietary ingredients) from a manufacturer and distributes the product under its own name, that person must meet all applicable CGMP requirements.

*Question 7.* We invited comment on whether specific controls are necessary for computer-controlled or assisted operations and how best to ensure that the software programs and equipment used to direct and monitor the manufacturing process are properly designed, tested, validated, and monitored.

Comments generally supported specific controls for computer-controlled or computer-assisted operations. One comment suggested requiring manufacturers to confirm, by adequate and documented testing, that their computer software programs perform their intended functions when computers are used as part of an automated production system having a significant and direct impact on product safety. Another comment suggested requiring that software programs and equipment used to direct and monitor manufacturing processes are properly designed, tested, evaluated, and monitored. The comment added that, if we consider imposing specific requirements on how firms document the adequacy of their computer-controlled or assisted operations, we should address those recommendations through a guidance document instead of issuing regulations.

We agree that computer-controlled or computer-assisted operations need to be properly designed, tested, evaluated, and monitored to ensure that the computers do what they are supposed to do. Manufacturers should confirm, by adequate and documented testing, that their computer software programs perform their intended functions because computer use as part of an automated production system has a significant and direct impact on product safety. Computers are an important controlling piece of equipment in the manufacture of dietary supplements because they often direct and control key steps or processes in the manufacture of dietary supplements. If computers do not operate correctly, the dietary supplements manufactured using those computers may be adulterated.

Several comments supported requirements for specific controls, but opposed using validation-of-operation mandates like those in the CGMP regulations for drugs. One comment suggested that we regulate computer-controlled and computer-assisted operations for dietary supplements in the same way that we regulate such operations in the pharmaceutical industry, but only where an operation is directly related to the product's concentration or purity. One comment suggested that we consider adopting the computer-controlled and computer-assisted procedures specified in the proposed infant formula CGMP.

We propose general requirements to ensure that equipment is suitable for its intended use. However, we seek comment, in the proposed rule, about whether we should include requirements, written procedures, and records for equipment verification and re-verification. We request comment on what verification manufacturers should be using in their computer-controlled or computer-assisted operations to ensure that a dietary ingredient or a dietary supplement that is produced is not adulterated during manufacturing. In addition, we request comment on whether we should issue guidance documents on verification procedures for use with computer-controlled or computer-assisted operations. Guidance documents generally represent FDA's advice or current thinking on a particular matter and are not binding on any person. In contrast, regulations create enforceable requirements that apply to all persons engaged in the same action or who make the same product.

As discussed in greater detail later in this document, certain processes are necessary to ensure that computer-controlled or computer-assisted equipment functions properly. This is because of the important role of such equipment in manufacturing. For example, if computer-controlled or computer-assisted equipment is used to control components, inprocess materials, and rejected materials unsuitable for use, the operation must function as expected to ensure that components suitable for use in manufacturing dietary ingredients and dietary supplements are not mixed up with components held under quarantine such as those components that have been rejected as unsuitable for use. If computer-controlled or computer-assisted operations are used for the addition and mixing of components, they must function properly to ensure that the correct components are added and appropriately mixed to avoid producing a dietary ingredient or dietary supplement that is adulterated. Computer-controlled or computer-assisted operations are not perfect; computers are subject to malfunctions and ''bugs'' (errors) in the software they use. Problems with data entered into the computer may produce unreliable results. For these reasons, specific controls for computer-controlled or computer-assisted operations are necessary to prevent the manufacture of an adulterated dietary ingredient or dietary supplement.

A few comments stated that no specific requirements for computer-controlled or computer-assisted operations are needed because computer hardware and software are simply specialized plant equipment so that no special regulations are needed.

We agree that computers are specialized pieces of plant equipment and, therefore, should be subject to additional requirements beyond those which would apply to plant equipment. Computers are specialized pieces of equipment because they are subject to malfunctions and ''bugs'' (errors) in the software, they are reliant upon data entered into a computer, and they may be used to perform important roles such as component or dietary ingredient identification, measuring components and dietary ingredients, and quarantining materials. Consequently, proposed § 111.30 would establish requirements for automatic, mechanical, or electronic equipment. The proposed requirements would cover, among other things, automatic equipment design, and routine calibration, inspection, and checks to ensure proper performance. As stated previously, we are seeking comment on whether we should include requirements for verification and re-verification of automatic, mechanical, or electronic equipment and processes and whether we should include requirements for computerized systems that are separate from requirements for other mechanical or automatic equipment. We discuss proposed § 111.30 in greater detail later in this document.

*Question 8.* 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 Hazard Analysis and Critical Control Point (HACCP), rather than the system outlined in the industry submission.

In the ANPRM, we noted that, because of the wide variety of dietary ingredients and dietary supplements and because of the heterogenous composition of the dietary supplement

industry, CGMPs based on HACCP principles may provide a more flexible and less burdensome regulatory framework for manufacturers and distributors than the approach set out in the industry submission.

Most comments opposed basing a CGMP regulation for dietary ingredients and dietary supplements on HACCP principles. Most comments supported applying traditional CGMP requirements on manufacturing, packaging, and holding to dietary ingredients and dietary supplements. In general, the comments that opposed requiring HACCP for dietary ingredients and dietary supplements asserted that: (1) A HACCP program would not be appropriate because HACCP focuses on microbial contamination of products that provide a favorable environment for growth of microbes that may be present, and these hazards are not a major concern for dietary supplements; (2) CGMPs are the best means of assuring the safety, quality, and composition of dietary ingredients and dietary supplements; (3) HACCP is not required for the food industry as a whole; and (4) HACCP would provide minimal incremental value at significant additional costs.

Other comments opposed mandatory HACCP regulations for dietary ingredients and dietary supplements, but said manufacturers could implement voluntarily HACCP instead. One comment, which supported voluntary implementation of HACCP, wanted manufacturers to be exempt from having to disclose HACCP records to any Federal agency.

HACCP principles can be applied to a broad range of manufacturing practices and HACCP principles are not solely focused on microbial contamination, but instead, are intended to identify and appropriately control steps in manufacturing where any type of adulteration can occur. Nevertheless, after considering the comments, we have decided to propose a CGMP approach for dietary ingredients and dietary supplements. We believe that CGMPs would establish a system of controls that, given the variations in size, technological sophistication, and regulatory experience among dietary ingredient and dietary supplement firms, would create a strong regulatory foundation throughout the industry.

You may voluntarily choose to implement a HACCP plan that meets the requirements of the National Advisory Committee on Microbiological Criteria for Foods, however, proposed part 111 would still apply to you (Ref. 42). Any HACCP plans that also are intended to meet the records requirements under proposed part 111 would be treated as records under this proposal.

*Question 9.* We invited comment on whether broad CGMP regulations will be adequate, or whether it will be necessary to address the operations of particular segments of the dietary supplement industry.

Most comments supported broad CGMP regulations covering all segments of the dietary supplement industry instead of specific regulations tailored to distinct segments of the industry. One comment stated that the differences between distinct segments of the dietary supplement industry, such as manufacturers of raw materials or distributors of finished products, are no more pronounced than similar segments in the food industry. Another comment stated that having numerous CGMPs could subject raw materials and dietary ingredients to multiple CGMPs, thus making manufacturing operations more complex. This comment also questioned whether issuing multiple regulations is necessary or economically justified in an era of limited corporate and government regulatory resources. Other comments emphasized the importance of ensuring that all dietary supplement manufacturers (*i.e.*, both small and large manufacturers, and foreign manufacturers planning to import dietary supplements into the United States) follow the same CGMP requirements.

In contrast, some comments supported drafting regulations for particular segments of the dietary supplement industry. One comment stated that certain stages of the manufacturing process, such as the distribution of raw dietary ingredients, should be more strictly and comprehensively regulated than other stages because potential hazards are more prevalent during these manufacturing stages. The comment stated that conversely, the holding, distribution, and sale of a finished dietary supplement may require less comprehensive regulations because they are subject to fewer potential hazards. Other comments supported different levels of safety testing for different types of dietary supplement products. For example, some comments said that products such as melatonin and dehydroepiandrosterone resemble drugs, so we should require safety testing in animals and humans and impose druglike CGMP requirements for manufacturing. Another comment stated that less stringent CGMPs would be appropriate for herbal dietary supplements because they have long histories of food use and safety.

We agree that some manufacturing operations are subject to greater hazards than others, and have drafted the proposed rule accordingly. For example, there are microbial hazards associated with raw botanicals. To address these hazards, the proposal would require that you perform tests on the botanicals. On the other hand, there are fewer hazards associated with holding and distributing finished dietary supplements, so the proposal would impose less comprehensive requirements for holding and distributing operations.

We are persuaded by the comments that support a broad CGMP regulation as preferable to multiple regulations focused on particular segments of the industry. We agree with the comments that multiple regulations might be confusing and burdensome, especially to firms that manufacture products that fall into multiple categories. For instance, it would be easier for regulated firms and for us if firms were required to adhere to one set of CGMP requirements rather than follow, for example, one set of CGMP requirements for vitamins and a different set of CGMP requirements for minerals.

We also recognize, though, that there may be some reasons to treat different types of dietary ingredients or dietary supplements differently in specific instances. For example, it may be appropriate to require one type of test for confirming the identity of amino acids and another type of test for confirming the identity of herbals. However, for the reasons discussed previously, we are proposing to establish one set of broad CGMP regulations for all types of products. Because we recognize that one set of specific requirements may not be appropriate for all types of dietary ingredients and dietary supplements, we have proposed regulations that allow manufacturers to develop practices to meet CGMP requirements. Depending on our experience with this proposed rule, we will consider whether we need to reevaluate our decision to establish one set of requirements for all dietary ingredients and dietary supplements.

We agree with the comments that the proposed rule should not make any distinction between dietary ingredients or dietary supplements made in the United States and those made in a foreign country. The proposed rule would require that foreign firms that want to export dietary ingredients and dietary supplements to the United States manufacture, package, and hold dietary ingredients and dietary supplements consistent with proposed part 111. Moreover, under this proposed rule, if a U.S. firm contracts with a

foreign firm to package dietary supplements for sale in the United States, the imported product would have to comply with the requirements in proposed part 111. In addition, the U.S. firm would be required to meet all applicable CGMP regulations under this proposed CGMP rule related to those activities in which it engages under the proposed rule. We invite comment on how best to ensure that dietary ingredients and dietary supplements exported to the United States have been manufactured, packaged, and held consistent with part 111.

This proposal does not include requirements for safety testing in animals and humans for certain types of dietary ingredients and dietary supplements. As discussed in several parts of this preamble, you are responsible for ensuring that the dietary ingredients or dietary supplements that you make are safe prior to marketing such products. Although we are focusing on the manufacturing steps in actual production and distribution of dietary ingredients and dietary supplements, there may be the need for specific regulations related to the use of animal tissue. We invite comment on whether there is a need for such specific regulations.

## III. Description of the Proposed Rule

This proposal will supercede what the agency said about the placement in Title 21 of the Code of Federal Regulations for any regulations resulting from the proposed rule for dietary supplements containing ephedrine alkaloids (62 FR 30678, June 4, 1997). That proposal included proposed revisions of part 111 and the table of contents for part 111 and we are now proposing those for 21 CFR part 112 (as explained below).

This proposal for dietary supplement CGMPs amends part 111 (21 CFR part 111), revising the heading from ''Current Good Manufacturing Practice for Dietary Supplements'' to ''Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements.'' Proposed part 111, with the heading ''Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements,'' includes only the CGMP for dietary supplements and the table of contents contains categorical CGMP practices in subparts A through H.

Further, we propose the heading and table of contents for part 112. Proposed part 112 has the heading ''Restrictions for Substances Used in Dietary Supplements.'' The table of contents for proposed part 112 includes: Subpart A ''General Provisions'' [Reserved]; Subpart B ''New Dietary Ingredients'' [Reserved]; and Subpart C ''Restricted Dietary Ingredients'' [Reserved]. Proposed subpart C would include restrictions for substances used in dietary supplements, such as the proposed rule for dietary supplements containing ephedrine alkaloids, if finalized.

These proposed changes are made for ease of use and clarity. CGMP regulations will be found more easily if located in one part, part 111, and clarity will be enhanced by using subparts to organize categorical CGMP practices. Similarly, restrictions for substances used in dietary supplements will be found more easily if located in one part, part 112, and clarity will be enhanced if the restrictions for substances used in dietary supplements are located in one subpart, subpart C.

The proposed part 111 consists of eight subparts. Several of the proposed provisions in the CGMP regulations for dietary ingredients and dietary supplements are similar to the CGMP regulations for food products at part 110. However, we edited the text in many cases to make the proposed rule easier to read and to understand consistent with plain language principles under the presidential memorandum of June 1, 1998 (Ref. 43). Some provisions are derived from the industry outline that we included in the ANPRM; others are derived from comments we received on the ANPRM or from our outreach efforts described previously. We also developed provisions based on our knowledge and expertise in the areas of dietary supplements, manufacturing, and contamination.

We tentatively decided to exclude certain CGMP requirements in part 110 for food products because they do not appear to be appropriate for dietary ingredients and dietary supplements. There are differences in the nature of the product (*i.e.*, conventional food versus dietary ingredients or dietary supplements) and in the manufacturing practices used to produce the product that require specific practices appropriate for dietary ingredients and dietary supplements. We invite comment on whether any provision from part 110 that we have not included should be included in this proposed CGMP for dietary ingredients and dietary supplements.

### *A. General Provisions (Proposed Subpart A)*

Proposed subpart A contains five provisions that would provide basic information to the reader.

#### 1. Who Is Subject to These Part III Regulations? (Proposed § 111.1)

Proposed § 111.1 entitled ''Who is subject to these regulations?'' describes the scope of the rule. Proposed § 111.1 states that you are subject to the requirements in part 111 if you manufacture, package, or hold a dietary ingredient or dietary supplement. As stated previously in this document, in our response to question 9 of the ANPRM, this proposed CGMP rule would apply to a wide variety of activities associated with the manufacture, packaging, and holding of dietary ingredients and dietary supplement products. These activities include labeling, testing, quality control, holding, and distribution. For example, if you contract with a manufacturer to perform an operation subject to proposed part 111, you will need to comply with those regulations directly applicable to the operation that you perform. For example, if you are a firm that has contracted with a dietary supplement manufacturer to package a dietary supplement, you are responsible for complying with all the regulations, including recordkeeping, that would otherwise be required of a manufacturer who does its own onsite packaging. Further, if you are a manufacturer and you contract with a firm to perform a particular manufacturing step, you would remain responsible for ensuring that such step is done in a manner that complies with the requirements in proposed part 111. As in the previous example, a manufacturer who contracts with a firm to package a product is still responsible for the actions of its contractor for the packaging activities and must ensure that its contractor complies with the applicable CGMP regulations.

Proposed part 111 also would apply to foreign firms that manufacture, package, or hold dietary ingredients and dietary supplements that are imported or offered for import into the United States, unless imported for further processing and export under section 801(d)(3) of the act, to persons who distribute such imported dietary ingredients and dietary supplements, and to persons who export dietary ingredients and dietary supplements from the United States, unless exported in compliance with section 801(e).

One comment to the ANPRM, relating to the scope of the CGMPs, requested an exemption from the CGMP for ''herbalist'' practitioners who individually manufacture dietary supplements for their clients.

We decline to exempt herbalist practitioners from the proposed rule. If

an herbalist practitioner introduces or delivers for introduction into interstate commerce, a dietary ingredient or dietary supplement, that practitioner must use the same good manufacturing practices as other manufacturers to ensure that their clients receive dietary supplements that are not adulterated. The risks of adulteration are not eliminated just because the practitioner is an herbalist. Therefore, we decline to exempt ''herbalist'' practitioners who manufacture dietary ingredients and dietary supplements. Herbalist practitioners who introduce or deliver for introduction into interstate commerce, a dietary ingredient or dietary supplement, are manufacturers who must meet CGMPs.

2. What Are These Regulations Intended To Accomplish? (Proposed § 111.2)

Proposed § 111.2, entitled ''What are these regulations intended to accomplish?'' discusses the purpose of the CGMP regulations. The proposal states that the regulations establish the minimum CGMPs that you must use to the extent that you manufacture, package, or hold a dietary ingredient or dietary supplement. By using the phrase ''to the extent,'' we mean that you must comply with the provisions that are applicable to you or to the operations that you perform and that, depending on the type of operations you perform, some provisions may not apply to you. For example, some provisions discuss requirements for automatic, mechanical, and electronic equipment; if you do not use such equipment, you would not have to comply with those provisions.

Our primary purpose in proposing these regulations is to protect consumers from adulterated and misbranded dietary supplements due to improper manufacturing, packaging, or holding practices. By observing CGMP regulations that require that dietary ingredients and dietary supplements are manufactured, packaged, or held in a controlled environment, manufacturers can ensure that dietary ingredients and dietary supplements are not adulterated or misbranded during manufacturing, packaging, and holding operations. Manufacturing, packaging, and holding dietary ingredients and dietary supplements under CGMPs will provide consumers with greater confidence that dietary supplements contain the dietary ingredients that they are supposed to contain and that these dietary ingredients were evaluated for their identity, purity, quality, strength, or composition. The CGMP regulations, if finalized as proposed, would require a manufacturer to establish specifications for the dietary ingredients and dietary supplements that it makes. Thus, under the proposed CGMPs, a dietary supplement with a particular dietary ingredient listed on its label must contain that particular dietary ingredient. Moreover, that dietary ingredient must meet certain specifications that the manufacturer establishes as to the purity, quality, strength, and composition. CGMPs are intended to ensure that a dietary supplement contains what the label says it contains. If it does not, the dietary supplement would not only be misbranded under section 403 of the act, but also would be adulterated under section 402(g) of the act.

3. What Definitions Apply to This Part? (Proposed § 111.3)

Proposed § 111.3 defines various terms used in proposed part 111. In general, we have used definitions that are similar to definitions in part 110 for food and other CGMP regulations. However, we have modified some definitions for ''plain language'' purposes under the presidential ''plain language'' memorandum (Ref. 43) and to make other definitions more appropriate for dietary ingredients and dietary supplements.

In some cases, we based a definition on provisions in the industry outline published in the ANPRM. However, we did not adopt all of the definitions in the industry outline. For example, the industry outline defined terms such as, ''adequate,'' ''composition,'' ''raw material,'' ''representable sample,'' and ''rework.'' We omitted those definitions from this proposal because the terms are generally understood, or because definitions for those terms are unnecessary for purposes of understanding the proposed rule.

Proposed § 111.3 states that the definitions and interpretations of terms in section 201 of the act apply to such terms when used in these regulations. Section 201 of the act defines various terms that appear throughout the act, including ''dietary supplement'' (*see* section 201(ff) of the act). Other terms in section 201 of the act, such as ''label'' (section 201(k) of the act) and ''pesticide chemical'' (section 201(q)(1) of the act), have a long history of use. The definitions and interpretations of such terms apply when we use those terms in this rule.

Proposed § 111.3 defines specific terms used in the proposal.

Proposed § 111.3 defines ''batch'' as ''a specific quantity of a dietary ingredient or dietary supplement that is intended to meet specifications for identity, purity, quality, strength, and composition, and is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.''

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).

Proposed § 111.3 defines ''batch number, lot number, or control number'' as ''any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, or holding of a batch or lot of dietary ingredients or dietary supplements can be determined.'' You should note that the proposed definition would have the batch, lot, or control number be ''distinctive,'' which means, for the purposes of this proposal, that it is unique in some fashion, and is not a reused number. Numbers must be distinctive because, if a problem involving a marketed dietary ingredient or dietary supplement later results, a distinctive batch number will make it possible for you to investigate the source of the problem and the manufacturing history for the batch. This would help you to take appropriate actions concerning that batch more quickly.

Proposed § 111.3 defines ''component'' as ''any substance intended for use in the manufacture of a dietary ingredient or dietary supplement including those that may not appear in the finished dietary ingredient or dietary supplement.'' Proposed § 111.3 states that ''component'' includes ingredients and dietary ingredients as described in section 201(ff) of the act. Under proposed § 111.3, components would include ingredients, dietary ingredients, manufacturing aids (such as solvents that are removed during manufacturing), and reagents that are used to synthesize a product.

Under the proposed definition of ''component,'' a component may or may not appear in the finished product. For example, solvents that are used to produce herbal extracts do not necessarily appear in a finished dietary supplement, but the proposed rule still would consider the solvents to be ''components.'' As another example, ingredients, such as cellulose (which is

used to make tablets) or gelatin (which is used to make capsules), might be used to produce dietary supplements; these ingredients remain in the finished product, but would be ''components'' under the proposed rule.

Proposed § 111.3 defines ''consumer complaint'' as:

> * * * communication that contains any allegation, written or oral, expressing dissatisfaction with the quality of a dietary ingredient or 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, which would include a consumer complaint. 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.

Communication about prices, package size or shape, or other matters that could not possibly reveal the existence of a hazard to health or do not concern the appearance, taste, odor, or quality of a dietary ingredient or a dietary supplement are not considered ''consumer complaints'' under the proposed rule. Consumer complaints related to an illness or injury related to a pharmacologically active substance of a dietary ingredient such as aristolochic acid would not be related to good manufacturing practices. The use of products containing aristolochic acid has resulted in several life-threatening adverse incidents. Aristolochic acids are potent carcinogens and nephrotoxins that are present, primarily, in plants of the family Aristolochiaceae. A product that contains a large amount of it may result in the rapid onset of acute toxicity symptoms in a consumer using the product. A product containing a small amount could be used for years with no apparent adverse effects, until serious, irreversible effects, such as renal failure, has occurred. Such adverse effects are related to a pharmacologically active substance of a particular dietary ingredient, aristolochic acid. Thus, for the purpose of this regulation, a communication from a consumer that contains any allegation, written or oral, related to the safety of the use of a product because it contained a particular dietary ingredient, *e.g.*, aristolochic acid would not be considered a ''consumer complaint.'' We consider that a dietary supplement containing a dietary ingredient such as aristolochic acid, a substance that is nephrotoxic and carcinogenic, is adulterated under section 402(a)(1), (f)(1)(A), and (f)(1)(D) of the act.

Proposed § 111.3 defines ''contact surface'' as:

> * * * any surface that contacts a component, dietary ingredient, or dietary supplement, and those surfaces from which drainage onto the component, dietary ingredient, or dietary supplement, or onto surfaces that contact the component, dietary ingredient, or dietary supplement ordinarily occurs during the normal course of operations.

Proposed § 111.3 gives some examples of contact surfaces, such as containers, utensils, tables, contact surfaces of equipment, and packaging. Under the proposed definition the term drainage includes both liquid and dry materials.

The proposed definition of ''contact surface'' is similar to the definition of ''food-contact surface'' in § 110.3(g), except we have used the terms ''component, dietary ingredient, or dietary supplement'' instead of food, and we have added several examples of contact surfaces. The proposed definition would include the inside of containers.

Proposed § 111.3 defines ''ingredient'' as ''any substance that is used in the manufacture of a dietary ingredient or a dietary supplement that is intended to be present in the finished dietary ingredient or dietary supplement.'' The proposed definition would explain that an ingredient ''includes, but is not necessarily limited to, a dietary ingredient as described in section 201(ff) of the act.'' Thus, under proposed § 111.3, an ''ingredient'' may be a substance that is present in the finished dietary ingredient or dietary supplement that is intended to have some activity (such as a vitamin, mineral, or amino acid), but could also be a substance that is not intended to have any activity (such as the gelatin used to make the capsule holding the dietary ingredients). This proposed definition and the proposed definition for ''component'' in proposed § 111.3 differ in that ''component'' includes the various materials used to manufacture a dietary supplement that may not appear in the final product. Because an ingredient is defined as a substance that is intended to be present in the finished dietary ingredient or dietary supplement and a component is defined as a substance that may or may not be included in the finished dietary ingredient or dietary supplement, all ingredients are components but not all components are ingredients.

Proposed § 111.3 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 ingredient or dietary supplement.'' In-process material differs from a component because in-process material is created and used during manufacturing. For example, assume you manufacture a dietary supplement in hard tablet form. During the manufacturing process, you mix various ingredients, and you add binding agents and water to mix the ingredients thoroughly before making individual tablets. The mixture would be an ''in-process material'' because it is a blend or processed material that you will use to make your dietary supplement.

Proposed § 111.3 defines ''lot'' to mean:

> * * * a batch, or a specific identified portion of a batch intended to have uniform identity, purity, quality, strength, and composition; or, in the case of dietary ingredient or dietary supplement produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is intended to have uniform identity, purity, quality, strength, and composition.

The proposed definition for ''lot'' is similar to the definition for ''lot'' in the proposed CGMP regulations for infant formula (61 FR 36154 at 36209, July 9, 1996), but would refer to ''identity, purity, quality, strength, and composition'' instead of ''character and quality'' to reflect the different characteristics of dietary ingredients and dietary supplements.

Proposed § 111.3 defines ''microorganisms'' as ''yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern.'' The proposed definition would include, but would not be limited to, species that:

- Have public health significance;
- Could cause a component, dietary ingredient, or dietary supplement to decompose;
- Indicate that the component, dietary ingredient, or dietary supplement is contaminated with filth; or
- Otherwise may cause the component, dietary ingredient, or dietary supplement to be adulterated.

The definition of ''microorganisms'' includes microorganisms of public health concern and microorganisms that are of sanitary concern. Proposed § 111.3 is similar to the definition of microorganism in § 110.3 but we added

''sanitary concern'' to the definition of microorganism. We added ''sanitary'' to clarify that we intend to include microorganisms of public health and sanitary concern. Although the term ''sanitary'' is not included in part 110, this change does not alter the generally recognized and scientific and legal meaning of the definition of ''microorganism'' in part 110, because part 110 is similarly concerned with sanitation. Under proposed § 111.3, *E. coli* O157:H7 would be a ''microorganism'' because it is a species that has public health significance. Other forms of *E. coli,* however, might not be of public health significance because not all forms of *E. coli* are pathogenic and present a public health risk. However, the presence of other forms of *E. coli* would be of sanitary concern.

One comment to the ANPRM objected to including viruses in a definition of ''microorganisms'' because it might imply that a manufacturer is able to demonstrate the absence of viral contamination in its dietary supplement.

We recognize that there are few effective virus detection methods and that the industry may be incapable of showing the presence or absence of specific viruses in its products. However, we have included viruses in the definition for ''microorganisms'' because animal tissues are used in the manufacture of dietary supplements, and the use of virus-containing tissue would adulterate the product. In order to ensure that animal tissue that may be used in or as a dietary ingredient does not contain viruses of public health significance, certain precautions may be needed to be taken in procuring and handling such tissue. We discuss in section III.A.4 of this document what precautions we are seeking comment on that manufacturers take to prevent the use of tissue that may contain viruses of public health significance for dietary ingredient or dietary supplement manufacture or to prevent the introduction of such viruses into a dietary ingredient or a dietary supplement.

Proposed § 111.3 defines ''must'' to indicate that you have to comply with a particular requirement. ''Must'' is the plain language term that replaces ''shall.''

Proposed § 111.3 defines ''pest'' as ''any objectionable insects or other animals including, but not limited to, birds, rodents, flies, mites, and larvae.'' Proposed § 111.3 is similar to § 110.3(j), although the proposed definition would add ''mites'' to the list of pests. We added mites to the definition of ''pest'' in this proposed rule because mites are capable of causing allergic reactions in persons who consume mite-contaminated foods (Ref. 44).

Proposed § 111.3 defines ''physical plant'' as ''all or parts of a building or facility used for or in connection with manufacturing, packaging, or holding a dietary ingredient or a dietary supplement.'' The proposed definition is similar to the definition of ''plant'' at § 110.3(k), except that we added the word ''physical'' before ''plant'' to distinguish between plants that are herbs, vegetables, and growing organisms, and buildings or facilities that are used in manufacturing, packaging, and holding a dietary ingredient or a dietary supplement. We also expanded the definition to cover the types of activities that would be subject to a CGMP rule for dietary ingredients and dietary supplements.

Proposed § 111.3 defines ''quality control'' as ''a planned and systematic operation or procedure for preventing a dietary ingredient or dietary supplement from being adulterated.'' A planned and systematic operation or procedure provides a framework of current and effective methods and procedures for each dietary ingredient or dietary supplement you manufacture that will prevent dietary ingredients and dietary supplements from being adulterated. We discuss quality control in more detail later in this document.

Proposed § 111.3 defines ''quality control unit'' as ''any person or group that you designate to be responsible for quality control operations.'' The quality control unit should consist of as many people as necessary to perform the quality control operations. Other provisions in this proposed rule address the quality control unit's authority and responsibilities, and we discuss those provisions later in this document.

Proposed § 111.3 defines ''representative sample'' as ''a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.'' By stating that the ''sample accurately portrays the material being sampled,'' we mean that it correctly represents and is typical of the material being sampled. It is important that the sample drawn accurately portrays the material being sampled because your analysis of the representative sample will be used to determine whether the material received is suitable for use in manufacturing or to determine that the dietary ingredient or dietary supplement is not adulterated and may be released for distribution. If the sample is not representative, you risk using a contaminated component or dietary ingredient in manufacturing and you may distribute an adulterated dietary ingredient or dietary supplement.

Proposed § 111.3 defines ''reprocessing'' as:

> * * * using, in the manufacture of a dietary ingredient or a dietary supplement, clean, unadulterated components, dietary ingredients, or dietary supplements that have been previously removed from manufacturing for reasons other than insanitary conditions and that have been made suitable for use in the manufacture of a dietary ingredient or dietary supplement.

The phrase ''for reasons other than insanitary conditions'' means that the component, dietary ingredient, or dietary supplement was removed from manufacturing because the incorrect amount of a component was added or other reason not due to insanitary conditions. However, the component, dietary ingredient, or dietary supplement that was removed from manufacturing because it became contaminated because of insanitary conditions, that is, it became contaminated with a microorganism of public health concern or a microorganism of sanitary concern, must not be reprocessed.

Proposed § 111.3 defines ''sanitize'' as:

> * * * to adequately treat equipment containers, utensils, or any other dietary product contact surface by applying cumulative heat or chemicals on cleaned food contact surfaces 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.

One comment to the ANPRM pointed out that the industry-drafted outline's definition of sanitize differed from FDA's *Food Code* definition of sanitization (Ref. 45).

The FDA ''Food Code'' is a reference that guides retail outlets, such as restaurants and grocery stores and institutions such as nursing homes in how to prevent foodborne illnesses from food that is consumed without further processing by the consumer. Because dietary supplements also are consumed without further processing by the consumer, the FDA ''Food Code'' definition also is appropriate for use in sanitizing contact surfaces used in the manufacture of dietary ingredients and dietary supplements. The FDA ''Food Code'' definition of sanitization is to apply cumulative heat or chemicals on

cleaned food contact surfaces 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. Because dietary supplements are consumed without further processing, and for consistency with other agency definitions and standards, we are persuaded to propose the FDA ''Food Code'' definition of ''sanitize.'' The agency believes that there may be a number of agents that can reduce the number of microorganisms present on contact surfaces. A tolerable level of risk may be achieved by interventions that have been validated to achieve a cumulative 5-log reduction in the target pathogens. However, we do not specify the manner in which the risk is reduced. The proposed requirement mandates that you validate that the control measures are both appropriate to their operation and scientifically sound. In many cases, processors 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 5-log reduction in the target pathogen, to ensure that the process is adequate to destroy microorganisms of public health significance or to prevent their growth. The agency requests comments on its approach to pathogen reduction. In particular, the agency requests comments on whether all contact surfaces should be subject to proposed § 111.3 ''sanitize.''

Proposed § 111.3 defines ''theoretical yield'' as ''the quantity that would be produced at any appropriate step of manufacture or packaging of a particular dietary ingredient or 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 would complement this definition by defining ''actual yield'' in proposed § 111.3 as ''the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular dietary ingredient or dietary supplement.'' Comparing theoretical yields to actual yields may help identify deviations or problems in the manufacturing or packaging process. To illustrate this point, you should understand that the theoretical yield is the quantity or amount that you expect to see at a particular step, while the actual yield is the quantity or amount that you actually obtain at a particular step.

Proposed § 111.3 defines ''water activity'' as ''a measure of the free moisture in a component, dietary ingredient, 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.'' The proposed definition is consistent with the definition at § 110.3(r) and 21 CFR 113.5(w) and 114.5(h). Water activity can play an important role in promoting microbial growth, and that, in turn, can play a part in the contamination of your components, dietary ingredients, and dietary supplements.

Proposed § 111.3 defines ''we'' as meaning the U.S. Food and Drug Administration.

Proposed § 111.3 defines ''you'' as ''a person who manufactures, packages, or holds dietary ingredients or dietary supplements.'' ''You'' is the recommended ''plain language'' term designed to make regulations easier to understand. In this proposed rule, ''you'' refers to any person, within the meaning of section 201(e) of the act, who engages in any activity covered by this proposed rule. You should note that ''you'' includes, but is not limited to, the owner of the manufacturing firm as well as supervisors responsible for ensuring that these CGMPs are followed. In other words, ''you'' can be the person who owns the dietary ingredient or dietary supplement company as well as persons who work for the company.

4. Do Other Statutory Provisions and Regulations Apply? (Proposed § 111.5)

Proposed § 111.5 would require that you comply with the regulations in proposed part 111, and with other applicable statutory provisions, and regulations under the act, related to manufacturing, packaging, or holding dietary ingredients or dietary supplements. Other statutory provisions or regulations that may apply to the manufacture, packaging, or holding of dietary ingredients or dietary supplements include, but are not limited to: (1) The PHS Act to prevent the introduction, transmission, or spread of communicable diseases; (2) part 110 (''Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food''); (3) part 113 (21 CFR part 113) (''Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers''); (4) part 123 (21 CFR part 123) (''Fish and Fishery Products''); (5) parts 70 through 82 (21 CFR parts 70 through 82) (for color additives); and (6) parts 170 through 189 (21 CFR parts 170 through 189) (for food additives). For example, a manufacturer who produces a dietary supplement that includes fish and fishery products, such as fish oil, would have to comply with HACCP regulations as required by part 123 as well as these CGMP provisions, if this rule is finalized, that apply to the dietary supplement. These other statutory provisions and regulations may apply because of the type of manufacturing process used or the type of ingredient in the dietary supplement.

Certain dietary ingredients, *e.g.*, an animal-derived ingredient, may require certain manufacturing, packaging, and holding practices because, without such practices, they may pose serious public health and safety concerns related to the transmission of communicable disease. For purposes of this discussion, the term ''animal-derived dietary ingredient'' refers to materials, substances, tissues, body fluids, or body secretions from animals, birds, reptiles, insects, and other living creatures and substances that may be derived from them. We do not consider human tissues and other parts of humans, other than human milk, to be eligible to be a dietary ingredient under section 201(ff) of the act because such products have not been used as a ''dietary substance for use by man to supplement the diet by increasing the total dietary intake'' (21 U.S.C. 321(ff)(1)(E)).

Certain animal-derived dietary ingredients, as well as the handling practices associated with such ingredients, may pose serious public health and safety risks, and therefore, may require regulations. Animal-derived materials, substances, and tissues have the potential to cause serious illnesses or injuries when ingested. For example, bovine colostrum is a substance that is used in dietary supplements (Ref. 46). Bovine colostrum which is the lacteal secretion which precedes milk after a cow gives birth, likely presents the same potential health risks as does milk. Bovine milk may contain pathogenic organisms capable of causing diseases in man such as tuberculosis, undulant fever, and gastrointestinal disease (Ref. 47). Such milk must be pasteurized in accordance with 21 CFR 1240.61. We have proposed a specific requirement at § 111.65(c)(5) that would require that you sterilize, pasteurize, freeze, refrigerate, control hydrogen-ion concentration (pH), control humidity, control water activity, or use any other effective means to remove, destroy, or prevent the growth of microorganisms and to prevent decomposition. This requirement, which would apply to bovine colostrum for use in a dietary supplement, is necessary to remove certain potential health risks. Milk also may contain contaminants, such as drug residues if the cow has been treated with such substances prior to beginning lactation,

that can cause serious adverse health effects in humans consuming the colostrum (Ref. 48). For example, if the colostrum contains drug residues, a dietary supplement containing colostrum could cause an adverse effect in a person who is allergic to the drug residue. In addition, some dietary supplements contain raw brain tissue or glands (Ref. 49) that have a high risk of containing the infective agent that causes bovine spongiform encephalopathy (BSE) if they originate from an animal infected with the disease (Ref. 37). In fact, dietary ingredients derived from different wild and domesticated animals may present microbiological and contaminant hazards that are unique to animal-derived dietary ingredients simply because the ingredient may not be amenable to physical treatments (for example, sterilization to eliminate pathogens) or there may not be appropriate methods to identify or correct a potential risk (as in the case of BSE or other transmissible spongiform encephalopathies (TSEs)).

The PHS Act is intended to prevent the introduction, transmission, or spread of communicable diseases (42 U.S.C. 264). Dietary supplements may be regulated under the PHS Act to the extent necessary to prevent the introduction, transmission, or spread of communicable diseases in intrastate and interstate commerce. Dietary supplements that contain animal-derived ingredients may carry infective agents that may not be able to be identified or that may be resistant to inactivation, as described previously. We are not aware of dietary supplement manufacturers' current procurement and handling practices of such dietary ingredients, nor the extent to which such dietary ingredients may be used. However, because the animal-derived dietary ingredients present important public health and safety issues, we are seeking comment on whether we should include in the final rule specific requirements for manufacturing, packaging, or holding animal-derived dietary ingredients. The U.S. Department of Agriculture (USDA) has imposed certain restrictions (*see* 9 CFR 94.18) on importation from certain regions of meat and edible products from certain animals. The USDA has determined that these regions present an undue risk of introducing BSE into the United States because BSE exists in the regions, because the regions have import requirements less restrictive than those that would be acceptable for import into the United States, and/or because of inadequate surveillance. Because there is no broadly applicable or validated diagnostic test available to manufacturers to identify BSE agent infected ruminant animals or BSE agent infected materials, the agency is considering whether to require, in our final rule, specific requirements under proposed § 111.35 that are designed to prevent the use of materials derived from certain animals from regions (''BSE Countries'') identified in 9 CFR 94.18. Such requirements would likely include manufacturer procedures and records and supplier certifications to ensure that a component, dietary ingredient, or dietary supplement is free of the agent of BSE. To prevent use of BSE agent-contaminated components, dietary ingredients, or dietary supplements, requirements for supplier certifications would likely include certification:

- Of the species of animal,
- Of the geographic origin of the animal,
- That no BSE was present in any of the animals in the herd from which the animal came and that none of the animals from the herd consumed mammalian-derived protein prohibited from use in ruminant feed,
- That any foreign manufacturer from which the material derived from animals was obtained:

1. Did not co-mingle material derived from animals from BSE countries with material derived from animals from non-BSE countries,
2. Established, validated, and followed plans or procedures to identify, track, and segregate material derived from animals from BSE countries from material derived from animals from non-BSE countries, and
3. Used dedicated manufacturing operations to prevent co-mingling of materials derived from animals from BSE countries with materials derived from animals from non-BSE countries.

Manufacturers that rely on supplier certifications to ensure that materials derived from animals are BSE-free would likely need to verify the reliability of supplier certifications by conducting supplier audits at appropriate intervals. We invite comment on whether there are other requirements that should be considered by FDA for supplier certification or other manufacturing requirements to prevent the use of BSE agent-contaminated components, dietary ingredients, or dietary supplements. These specific requirements may be issued under the authority of the act or may need to be issued under PHS Act authority and may need to include relevant remedies available under the PHS Act. In addition, we invite comment on whether there are animal-derived materials from BSE countries that do not present a safety concern and, if so, whether FDA should consider exempting such materials from a possible requirement that would prevent the use of animal-derived materials from BSE countries in dietary supplements and why. The agency will consider whether to include, in the final rule, provisions specifically related to the manufacture, packaging, and holding of animal-derived dietary ingredients or dietary supplements. One of the more obvious and serious hazards is the transmission of TSE (Ref. 37). We have 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 published a notice in the **Federal Register** of August 29, 1994 (59 FR 44592), entitled ''Bovine-Derived Materials; Agency Letters to Manufacturers of FDA-Regulated Products'' (Ref. 50). The notice, in part, published the November 1992 and December 1993 letters to manufacturers. In November 1992, we wrote to manufacturers of dietary supplements to alert them to the developing concern about TSEs in animals and Creutzfeldt-Jakob Disease in humans and recommended that they investigate the geographic 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. In December 1993, we issued a letter recommending against the use of bovine-derived materials from cattle that resided in, or originated from, BSE countries in FDA-regulated products. In this letter, we recommended that manufacturers: (1) Identify bovine-derived materials in their products and identify all countries where the animals used to produce the materials had lived, (2) maintain traceable records for each lot of bovine materials and for each lot of FDA-regulated product using these materials, (3) document the country of origin of the live animal source of any bovine-derived materials used in the manufacture of the regulated products, and (4) maintain copies of the records identified above for FDA-regulated products manufactured using bovine-derived materials at foreign sites or by foreign manufacturers. To assure the safety and suitability for human use of animal-derived biologics, our Center for

Biologics Evaluation and Research (CBER) has developed guidances for industry that describe steps that manufacturers should take. For example, CBER guidances have recommendations that address viral safety, infections, disease risks, and BSE-risk reduction of biologic products that are animal-derived (*see* 63 FR 51074, September 24, 1998, and 63 FR 50244, September 21, 1998) (Refs. 51 and 52). Because we believe 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 are 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, therefore, invite comment on whether there should be specific CGMP requirements for the use of animal-derived materials, substances, or tissues in dietary ingredients and dietary supplements. We invite comment on these issues and specifically on whether there is a scientific basis for FDA to treat animal-derived dietary ingredients in a manner that is 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. We also invite comment on our legal authority with respect to these issues.

5. Exclusions (Proposed § 111.6)

Proposed § 111.6 would state that these CGMP regulations do not apply to a person engaged solely in activities related to the harvesting, storage, or distribution of raw agricultural commodities that will be incorporated into a dietary ingredient or dietary supplement by other persons. This proposed exclusion is similar to the exclusion in § 110.19 for raw agricultural commodities. Accordingly, persons who engage in such activities related to raw agricultural commodities (which are defined in section 201(r) of the act), although not subject to these proposed CGMP regulations under section 402(g) of the act, would continue to be subject to other adulteration provisions in section 402 of the act.

We recognize that including in the proposed rule persons who engage in the activities related to the harvesting, storage, or distribution of such commodities, as described previously, could reduce the risk of microbial contamination in dietary ingredients and dietary supplements. Nevertheless, the proposal does not contain requirements for persons handling such commodities before distribution to a dietary ingredient or dietary supplement manufacturer because the scientific basis for reducing or eliminating pathogens in various settings is evolving. We invite comments on whether we should include provisions in the CGMP proposal that would include persons who handle raw agricultural commodities.

Even though the proposed rule would not cover persons who harvest or otherwise handle raw agricultural commodities before distribution of these commodities to a dietary ingredient or dietary supplement manufacturer, we recommend some practices to help you minimize microbial food safety hazards in such commodities that you may use in a dietary ingredient or dietary supplement. We recommend that you adapt, to your practices, the good agricultural practices (GAPs) and good manufacturing practices for fruits and vegetables that we issued as a guidance document: ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (Ref. 53). This guidance document includes recommended GAPs for water, worker health and hygiene, sanitary facilities, field sanitation, packing, and transportation. Those who harvest, store, or distribute raw agricultural commodities for incorporation into dietary ingredients or dietary supplements should adapt these practices to their specific operations.

*B. Personnel (Proposed Subpart B)*

Proposed subpart B contains three provisions dealing with personnel matters. In general, the proposed provisions are similar to the current CGMP requirements for food personnel in § 110.10.

1. What Microbial Contamination and Hygiene Requirements Apply? (Proposed § 111.10)

Individuals who handle components or dietary supplements may affect the purity or quality of those components or dietary supplements if they fail to take precautions to guard against microbial contamination or other types of contamination. For example, an employee who has an illness could unintentionally transfer bacteria or viruses causing such illness to a dietary supplement by simply handling the dietary supplement.

Proposed § 111.10(a), therefore, would require that you take measures to exclude from any operations any person who might be a source of microbial contamination of any material including components, dietary ingredients, dietary supplements, or contact surfaces used in the manufacture, packaging, or holding of a dietary ingredient or a dietary supplement. We based proposed § 111.10(a) on similar requirements in § 110.10.

Proposed § 111.10(a)(1) would require that you exclude any person who, by medical examination or supervisory observation, is shown to have, or appears to have an illness, open lesion (such as a boil, sore, or an infected wound), or any other abnormal source of microbial contamination from any operations, which may be expected to result in microbial contamination of components, dietary ingredients, dietary supplements, or contact surfaces, from working in any operations until the condition is corrected. For example, if an employee tells you that his or her physician has diagnosed that the employee has a fever, and the employee normally handles your dietary supplements, you must take steps to ensure that the employee does not come into contact with your dietary supplements because the fever may suggest that the employee has an infection and there is a reasonable possibility of contamination. Likewise, if your supervisors see that an employee has an open wound or sore, and the employee normally handles dietary ingredients, you must take steps to ensure that he or she is excluded from handling dietary ingredients because the open wound or sore could be a source of microbial contamination and because there is a reasonable possibility of contamination.

Proposed § 111.10(a)(2) would require that you instruct your employees to notify their supervisor(s) if they have, or if there is a reasonable possibility that they have, a health condition that could contaminate any components, dietary ingredients, dietary supplements, or any contact surface.

Proposed § 111.10(b) would apply if you work in operations where adulteration of components, dietary ingredients, dietary supplements, or contact surfaces may occur. The proposal would require that you use hygienic practices to the extent necessary to protect against contamination of those components, dietary ingredients, dietary supplements, or contact surfaces.

These hygienic practices would include, but would not be limited to:

- Wearing outer garments in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or any

contact surface. Outer garments may include gowns or aprons;

• Maintaining adequate personal cleanliness;

• Washing hands thoroughly (and sanitizing if necessary to protect against contamination with microorganisms) in an adequate hand-washing facility:

1. Before starting work; and

2. At any time when hands may become soiled or contaminated. Hands may become soiled or contaminated after meals or after using the bathroom;

• Removing all unsecured jewelry and other objects that might fall into components, dietary ingredients, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods when you manipulate components, dietary ingredients, or dietary supplements by hand. If the hand jewelry cannot be removed, the proposal would require that it be covered by material that is intact, clean, and in sanitary condition that effectively protects against contamination of your components, dietary ingredients, or dietary supplements, or contact surfaces.

• Maintaining gloves used in handling components, dietary ingredients, or dietary supplements in an intact, clean, and sanitary condition;

• Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other hair restraints;

• Not storing clothing or other personal belongings in areas where components, dietary ingredients, dietary supplements, or any contact surfaces are exposed or where contact surfaces are washed;

• Not eating food, chewing gum, drinking beverages, and using tobacco products in areas where components, dietary ingredients, dietary supplements, or any contact surfaces are exposed or where contact surfaces are washed; and

• Taking any other necessary precautions to protect against contamination of components, dietary ingredients, dietary supplements, or contact surfaces by microorganisms, filth, or other extraneous materials, including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

Each of these procedures is necessary because good personal hygiene should help prevent contamination from microbial sources (such as bacteria) as well as from nonmicrobial sources (such as dirt and hair).

We seek comment on whether we should require, in a final rule, that you establish and follow written procedures to ensure that you comply with the requirements of that section. As stated previously, we invite comment on whether such written procedures should be required in a final rule, and whether there are other procedures, that we should include in a final rule. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

A comment to the ANPRM stated that any requirements on disease control should be limited to manufacturing, processing, and handling of raw agricultural material and are not appropriate for manufacturing dietary supplements derived from chemicals. The comment stated that chemical processes are carried out in closed pipes and vessels, so the risk for human contamination is very low. The comment, therefore, said that FDA should allow workers who have wounds to continue working in manufacturing operations.

We disagree that the regulations on disease control should be limited to manufacturing, processing, and handling raw agricultural material. Because contamination may occur at any time during manufacturing, packaging, or holding operations, requirements concerning disease control must apply to all operations where a person may contaminate a component, dietary ingredient, dietary supplement, or contact surface. For example, an employee could contaminate a dietary supplement (of agricultural origin or synthetic origin) or contact surface during packaging operations. However, if we adopted the comment's suggested limitation, contamination of a synthetic dietary supplement could occur, and there would be no regulatory requirement to guard against such contamination.

As for employees with open wounds, proposed § 111.10(a) would require that you exclude a person with an open lesion or any other abnormal source of microbial contamination from any operation which may adulterate the component, dietary ingredient, dietary supplement, or contact surface. Whether the proposed rule would require that you exclude a person with an open lesion or another abnormal source of microbial contamination from working in a closed system area, such as when the product is contained completely in closed pipes or vessels, would depend on whether, as a result of exposure, there would be a reasonable possibility of the component, dietary ingredient, dietary supplement, or contact surface becoming contaminated. Thus, when a dietary ingredient or dietary supplement is manufactured in a completely closed system, this proposed requirement on open lesions might not apply if there is no reasonable possibility of contamination. However, you must take the measures that would be required by § 111.10(a) if there is a reasonable possibility that any person might cause contamination of components, dietary ingredient, dietary supplements, or contact surfaces.

Comments to the personnel provisions, and other provisions, stated that the industry-drafted outline used phrases such as ''includes, but are not limited to,'' when giving examples of how to comply with various requirements. The comments suggested that this phrase be changed to ''may include'' to clarify that items that follow the phrase are simply examples of how to comply with a particular requirement and are not binding or do not represent an exhaustive list of examples.

We decline to draft the proposal as suggested by the comments because we do not agree that when we state ''includes, but are not limited to,'' we are providing examples of how to comply with the regulations. When we state that a regulation requires a manufacturer, packager, or holder to establish certain practices which ''includes, but is not limited to'' a list

of procedures or activities, we are stating that compliance with the regulation requires that you adopt, at the minimum, the procedures or activities listed in the regulation. Therefore, when we state ''includes, but is not limited to,'' we mean that the list of procedures or activities following the ''includes'' statement is a list of requirements.

2. What Personnel Qualification Requirements Apply? (Proposed § 111.12)

Proposed § 111.12 would establish basic qualification requirements for employees. Proposed § 111.12(a)(1) would require that you have qualified employees to manufacture, package, or hold dietary ingredients or dietary supplements. We are not proposing a general standard for determining how many employees are necessary, but there should be enough to manufacture, package, or hold dietary ingredients or dietary supplements consistent with these proposed CGMPs. A one-person operation is not precluded provided that one person is sufficient to achieve, maintain, and document CGMPs. However, general manufacturing practice suggests the need for a minimum of two persons, the first to perform the work and a second person to check the work performed to ensure that a manufacturing deviation or an unanticipated occurrence is not overlooked. However, we leave the determination of the actual number of employees necessary to your discretion. As stated previously, we invite comment on whether there is a minimum number of employees needed to manufacture dietary ingredients or dietary supplements.

Proposed § 111.12(a)(2) would require that each person engaged in manufacturing, packaging, or holding must have the training and experience to perform the person's duties. Training is necessary to ensure that employees know how to correctly and fully perform the operations in question and to ensure that the employees are competent to produce an unadulterated product. The extent and frequency of the training is left to the manufacturer's discretion. The extent and frequency of training needed for your employees will depend on the scope of the employee's activities and experience. For example, training may be necessary when you hire new employees, when employees engage in new activities, when your physical plant implements new manufacturing practices, or when you add new equipment or new processes to manufacturing. For example, an employee responsible for measuring ingredients during batch production should have sufficient training or expertise to perform those functions. If that employee does not know how to measure correctly, the employee may add too much of an active ingredient, which may cause the product to be adulterated. Thus, proposed § 111.12 would establish requirements for your employees.

We invite comment on whether we should require, in a final rule, a requirement that you document and keep records regarding each employee's training. We believe that the records, if required, should show the content and date of the training. Such records may be useful in determining whether an employee has received the training necessary to perform his or her duties. We invite comment on not only whether such records should be required in a final rule, but also what types of information such records should contain.

You may use consultants to advise you on any aspect of the manufacture, packaging, or holding of dietary ingredients or dietary supplements. Any consultant you use should be qualified by training and experience to provide the advice they give to you. We invite comment on whether we should require, in a final rule, that you document each consultant's name, address, and qualifications and include a description of the services that the consultant provided. Such records may assist you in knowing who to contact and where to contact him or her if questions arise concerning the advice given.

A comment to the ANPRM suggested that the employee qualification requirements in the industry outline should, in part, state that ''proper education, training, or experience'' is required instead of ''proper education, training, and experience'' is required (emphasis added).

We disagree with the use of ''or'' instead of ''and.'' We omitted the term ''proper education'' because ''training'' may be considered a form of ''education.'' However, the proposed rule uses the conjunction ''and'' because, while some might consider ''experience'' to be a form of ''training,'' most consider ''experience'' to be knowledge that a person gains over time as he or she becomes increasingly familiar with a particular action or piece of equipment.

Training, however, may not just include on-the-job training, but may include some type of educational experience derived from attending classes or lectures or some other formal instruction on a particular subject. Some positions not only require the employee to have experience or training on the job, but also require that the employee have the appropriate educational background, for example, to understand the significance of using a particular test method or understanding the significance of a processing deviation and how to respond to such deviation. The word ''and'' includes situations where on-the-job training may be adequate and also situations where educational training may be required. Therefore, proposed § 111.12(a)(2) refers to ''training and experience.''

3. What Supervisor Requirements Apply? (Proposed § 111.13)

Proposed § 111.13 would establish general supervision requirements and is similar to a provision that appeared in the industry-drafted outline. Proposed § 111.13(a) would require that you clearly assign to qualified supervisory personnel the responsibility for ensuring that all CGMP requirements in part 111 are met. You should assign an adequate number of qualified personnel to supervise the manufacturing, packaging, or holding of dietary ingredients and dietary supplements. We are not proposing a general standard for determining how many supervisors are necessary and a one-person operation is not precluded provided that one person is sufficient to supervise CGMPs. As stated previously, we invite comment on whether there is a minimum number of qualified personnel to supervise the manufacturing, packaging, or holding of dietary ingredients or dietary supplements. Proposed § 111.13(b) would require you and your supervisors to be qualified by training and experience to supervise.

Making supervisors responsible for compliance with the regulations would be an important step in manufacturing, packaging, and holding dietary ingredients and dietary supplements under conditions that will not cause adulteration and misbranding. We believe that clearly designating compliance responsibilities to individuals increases the likelihood of compliance with the regulations.

One comment to the ANPRM questioned why supervisory personnel must be ''qualified'' when the food CGMP regulations require supervisory personnel to be ''competent'' (see § 110.10(d)).

We consider the terms to be equivalent in this case. The *Webster's II New Riverside University Dictionary* defines competent as ''able to perform as required: competent'' and further defines ''qualified'' as ''having met the requirements for a specific position or

task'' (Ref. 54). Therefore, we consider the words ''qualified'' and ''competent'' in proposed § 111.13 and § 110.10(d), respectively, should be considered synonymous.

Another comment to the ANPRM questioned making supervisors responsible for ensuring compliance by all personnel with all CGMP requirements. The comment stated that absolute compliance with each and every CGMP requirement cannot be ensured, but that requiring a supervisor to be responsible may make the supervisor personally liable in the event of noncompliance.

Proposed § 111.13(a) would require that manufacturers assign responsibility to qualified supervisory personnel. Doing so will help ensure that the CGMPs are followed. In general, if the proposed rule is finalized, manufacturers, packagers, and holders would be responsible for complying with these CGMP requirements and for ensuring that they assign responsibility to qualified supervisors. We consider many factors when we take enforcement action, and so the facts surrounding a CGMP violation will influence the type of enforcement action we take. The manufacturer is responsible under § 111.13(a) for ensuring that qualified supervisory personnel are assigned to oversee the implementation of these CGMPs.

*C. Physical Plant (Proposed Subpart C)*

Proposed subpart C consists of provisions intended to help prevent contamination from your physical plant. These provisions are similar to the food CGMP requirements found in §§ 110.20, 110.35, and 110.37 which pertain to buildings and facilities.

We have not proposed 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, dietary ingredients, or dietary supplements. In order to limit the burden to manufacturers, FDA is not proposing such requirements. However, we invite comment on whether such requirements should be included in a final rule. Section § 110.20(a), identifies several methods necessary for adequate ground maintenance, such as:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of your physical plant so that it does not attract pests, harbor pests, or be used by pests for breeding;
- Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed;
- Adequately draining areas that may contribute to the contamination to food by seepage, filth, other extraneous materials, or by providing a breeding place for pests; and
- Adequately operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

For example, rodents, insects, and other pests may be attracted to garbage, and if you do not take adequate steps to remove or dispose of garbage, you may be risking contamination from those rodents, insects, or other pests. Rodents, insects, and other pests are sources of feces, hair, and other potential contaminants (Refs. 55 and 56). We invite comment on whether we should require, in a final rule, that you take these steps and/or other steps to protect against contamination.

1. What Sanitation Requirements Apply to Your Physical Plant? (Proposed § 111.15)

Proposed § 111.15(a), like § 110.35(a), would require that you keep your physical plant in a clean and sanitary condition and in sufficient repair to prevent contamination of components, dietary ingredients, dietary supplements, or contact surfaces. For example, holes in your physical plant's walls or windows could allow pests or contaminants to enter, so proposed § 111.15(a) would require that you repair those holes.

Proposed § 111.15(b) pertains to cleaning compounds, sanitizing agents, and pesticides you use. The proposal is similar to § 110.35(b) and, in essence, would require that you use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and are safe and adequate under the conditions of use. By saying that the cleaning compounds and sanitizing agents should be ''free from microorganisms,'' we mean that your use of those cleaning compounds and sanitizing agents should not contaminate your components, dietary ingredients, dietary supplements, or contact surfaces with microorganisms. We are proposing this requirement because microorganisms, if present in your cleaning compounds or sanitizing agents, can contaminate your contact surfaces or deactivate the sanitizing agent and, as a result, adulterate your components, dietary ingredients, dietary supplements, or contact surfaces. We advise that you should verify that cleaning compounds and sanitizing agents are free from contamination by microorganisms of public health significance and are safe and adequate under their conditions of use. Such verification may include buying these substances under a supplier's guarantee or certification or you may examine them for contamination.

Several comments on the industry outline published in the ANPRM objected to the idea 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.'' The comments stated that such language is unnecessary and may be interpreted as too restrictive and that manufacturers should be able to determine the appropriate means of assuring compliance.

We agree with the comments that you may determine the appropriate means of assuring compliance with this regulation. The proposed rule would not require that you follow any particular method for assuring compliance; instead, the proposal would give you the flexibility to decide how to ensure that your cleaning compounds and sanitizing agents are free from contamination and are safe and adequate under the conditions of use.

Proposed § 111.15(b)(2) would require that you not use or hold toxic materials in a physical plant in which contact surfaces, components, dietary ingredients or dietary supplements are manufactured or exposed, unless those toxic materials are necessary:

- To maintain clean and sanitary conditions,
- For use in laboratory testing procedures,
- For maintaining or operating the physical plant or equipment, or
- For use in the physical plant's operations.

If at least one of the listed conditions is not met, you must not use or hold the toxic material because there would be no reason to risk contamination from exposure to such material if it is not necessary to your operations.

Proposed § 111.15(b)(3) would require that you identify and hold toxic cleaning compounds, sanitizing agents, pesticides, and pesticide chemicals in a manner that protects against contamination of components, dietary ingredients, dietary supplements, and contact surfaces. You must take steps to store your toxic materials in a way that prevents them from contaminating your dietary ingredients and dietary supplements. If such products were stored in manufacturing areas or where dietary ingredients or dietary

supplements may be otherwise exposed to such products, those toxic materials may come in contact with the dietary ingredients or dietary supplements and thereby contaminate them. In addition, clearly identifying the containers in which such toxic materials are held will prevent accidental use.

One comment to the ANPRM objected to the provision in the industry outline that would require manufacturers to register and use rodenticides, insecticides, and fungicides in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act and to follow all relevant Federal, State, and local government requirements. The comment said the requirement would be redundant with other regulations.

Although this CGMP proposed rule does not propose a requirement that you follow all relevant Federal, State, and local government requirements when applying, using, or holding toxic cleaning compounds, sanitizing agents, and pesticides, the proposed rule does not relieve you from such obligations.

Proposed § 111.15(c) pertains to pests. Proposed § 111.15(c)(1) would require that you exclude animals or pests from all areas of your physical plant, while proposed § 111.15(c)(2) would require that you take effective measures to exclude pests from your physical plant and to protect against the contamination of components, dietary ingredients, dietary supplements, or contact surfaces. Therefore, if you have pests in your physical plant, you must take immediate action to get rid of them. In addition, you must take measures to prevent those and any other type of pests from entering your physical plant.

You should note that, like § 110.35(d), proposed § 111.15(c)(1) would allow guard dogs and guide dogs in your physical plant if their presence will not result in the contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.15(c)(3) would require that you not use insecticides, fumigants, fungicides, or rodenticides unless you take precautions to protect against contamination of your components, dietary ingredients, dietary supplements, or contact surfaces. For example, some pesticides may cause adverse effects in humans, so you must take precautions to ensure that any pesticides you use will not contaminate your components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.15(d) would apply to water supplies and is patterned after the food CGMP requirement at § 110.37(a). 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:

- Manufacturing dietary ingredients or dietary supplements;
- Making ice that comes into contact with components, dietary ingredients, dietary supplements, or contact surfaces;
- Cleaning surfaces; and
- 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 surfaces, at a minimum, comply with the National Primary Drinking Water (NPDW) regulations prescribed by the Environmental Protection Agency (EPA) and any State and local government requirements. (EPA's NPDW regulations can be found at 40 CFR part 141.)

Proposed § 111.15(d) would require that you use water that is of safe and sanitary quality in all aspects of your operation where, if such water was not used, could result in contamination and adulteration of your dietary ingredients and dietary supplements. Further, under proposed § 111.15(d)(2), in any operation where water contacts components, dietary ingredients, dietary supplements or any contact surfaces, the water must comply with the EPA's NPDW regulations. We believe that the EPA's NPDW water regulations are necessary because contaminated water can contaminate dietary ingredients and dietary supplements both when used as an ingredient in the dietary ingredient or dietary supplement and when contaminated water is allowed to enter the product indirectly, as can occur, for example, when water is used to cool a product or to clean a contact surface.

We recognize that, for some operations, you may want to use water that is more pure or of higher quality than that required under the NPDW regulations. For example, to ensure the purity of your dietary supplements, you might use water that has gone through water purification and filtering equipment to ensure that the water is clean and sterile. In contrast, to clean contact surfaces and other surfaces, sterilized water may be unnecessary because a contact surface that is exposed to the environment will not remain sterile; airborne microorganisms and microorganisms on your employees will find their way onto the contact surface, thereby rendering it nonsterile. Proposed § 111.15(d) would not prevent you from using water that is more pure than that required under the NPDW regulations. Proposed § 111.15(d) provides you with the flexibility to raise your water quality above the minimum criteria to meet your particular manufacturing needs. We acknowledge that foreign firms may not be subject to EPA water requirements or adhere to EPA requirements. Nevertheless, water quality is an important part of CGMPs, so we invite comment on our proposed requirement that does not distinguish between foreign or domestic requirements, and, therefore, would require foreign firms to meet the NPDW regulations.

A number of comments to the ANPRM suggested that we should require the use of potable water (water that is fit to drink) or a higher quality water or establish potable water as the minimum quality water standard. One comment stated that the industry outline, by referring to potable water, prevents the use of water whose quality exceeded a potable water standard because a higher quality water would not be in compliance.

We agree that potable water should be a minimum water quality standard, and proposed § 111.15(d) would reflect that standard. Proposed § 111.15(d)(1) would require water to be ''safe and of adequate sanitary quality.'' Water that is ''safe and of adequate sanitary quality'' is or should be potable. Proposed § 111.15(d)(2) would require water that contacts components, dietary ingredients, dietary supplements, or contact surfaces to meet, at a minimum, EPA's NPDW regulations and State and local requirements. Water meeting these requirements is potable.

Please note that proposed § 111.15(d) does not prevent you from using water that is more pure or of higher quality than that required under EPA's NPDW regulations. We reiterate that proposed § 111.15(d) would establish minimum water quality standards.

Proposed § 111.15(d) does not make any distinctions between water from public sources and water from private sources. Consequently, if you use water from private sources, you would need to ensure that the water meets the minimum water quality standards in proposed § 111.15(d). For example, if you use a well as your water source, you would need to ensure that the well design meets government water quality standards and you may need to perform appropriate water treatment procedures, including filtration, sedimentation, and chlorination. These actions are necessary because private water sources, such as surface waters or water from shallow wells, may be subject to microbiological, chemical, or radiological contamination. For

example, fertilizer runoff can enter streams and contaminate surface water. Contaminants in the ground may enter a well and contaminate well water. Therefore, it is important that water from any source comply with the requirements set out in proposed § 111.15(d).

Another comment to the ANPRM suggested that a potable water standard is inappropriate for use in manufacturing dietary ingredients and dietary supplements from chemicals. The comment would limit the use of potable water to manufacturing, processing, and handling of vegetables, ready-cooked dishes, etc.

We disagree with the comment. If water is not suitable for drinking (nonpotable), the water may contain microorganisms or contaminants that will contaminate your dietary ingredients or dietary supplements. For example, water from private sources may be untreated, so it may be contaminated by pesticides due to water runoff from fields or may contain microorganisms, algae, particulates, etc. Therefore, proposed § 111.15(d) would require that you use water that is of safe and sanitary quality, regardless of whether you use natural or synthetic components to make dietary ingredients and dietary supplements.

Proposed § 111.15(d)(3) would require that you have documentation or otherwise be able to show that the water that contacts components, dietary ingredients, dietary supplements, or any contact surface meets the water quality standard in proposed § 111.15(d)(2). The proposal would not prescribe any particular type of documentation or method for showing water quality, but you should remember that water is used as a component in manufacturing dietary ingredients and dietary supplements would fall within the definition of ''component,'' so it should meet whatever specifications you establish for component identity, purity, quality, strength, and composition. We discuss requirements for the identity, purity, quality, strength, and composition of components later in this section when we describe proposed § 111.35, ''What production and process controls must you use?''. Proposed § 111.15(d)(3) would be similar to a provision in the drug CGMP regulation at 21 CFR 211.48(a) and the proposed requirement in the infant formula proposed rule (61 FR 36154 at 36211), which requires that water meet EPA's drinking water requirements in 40 CFR part 141.

Proposed § 111.15(e) is similar to the plumbing requirements in the food CGMPs at § 110.37(b). Proposed § 111.15(e) would require your physical plant's plumbing to be adequate size and design and to be adequately installed and maintained to:

- Carry sufficient amounts of water to required locations throughout the physical plant;
- Properly convey sewage and liquid disposable waste from your physical plant;
- Avoid being a source of contamination to components, dietary ingredients, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition;
- Provide adequate floor drainage in all areas where floors are subject to flooding-cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
- Not allow backflow from, or cross-connection between, piping system that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary ingredients or dietary supplements, or cleaning contact surfaces, or for use in bathrooms and hand washing facilities.

This provision is intended to ensure that your plumbing system does not adversely effect the water in your physical plant. If the plumbing system is not adequately installed and maintained, it may contaminate your water supply and, in turn, contaminate your components, dietary ingredients, and dietary supplements through direct contact, such as when you use water to make the products, or indirect contact, such as when the contaminated water is used on a contact surface.

In addition to the water directly contaminating your components, dietary ingredients, dietary supplements, or contact surfaces, standing water can cause contamination by attracting pests or becoming a breeding ground for microorganisms. Therefore, the proposal would require your plumbing system to have adequate drainage and would not allow backflows or cross-connections in your plumbing system because backflows from a nonpotable water system to a potable water system under negative pressure conditions could contaminate your water system (Ref. 57).

A comment to the ANPRM stated that requiring a physical plant's plumbing to carry sufficient amounts of water to required locations throughout the plant was too vague. The comment stated the water is not needed in many operations in the plant, and so firms should be able to decide the location and availability of water throughout their own physical plants.

The comment may have misinterpreted the ANPRM. Proposed § 111.15(d) would not require water to be available in all parts of a physical plant. In areas where water is unnecessary, we would not expect you to make water available or to have any particular quantity of volume of water available. However, there are areas where water is necessary to ensure that any unadulterated dietary ingredient or dietary supplement is manufactured, packaged or held. In those areas where water is necessary, your plumbing must carry sufficient amounts to those locations.

Proposed § 111.15(f) would require that you dispose your physical plant's sewage into an adequate sewage system or through other adequate means. This proposed provision is similar to the sewage provisions at § 110.37(c). Proper sewage disposal is essential to ensure that you maintain your manufacturing facility in a sanitary condition, and this would include protecting the processing environment against pathogenic microorganisms shed in fecal material. For example, bathroom floors can become contaminated with pathogens if your sewage disposal system fails to remove fecal material. Employees using those bathrooms, in turn, can transport those pathogens into your processing areas and contaminate components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.15(g) would apply to bathrooms. Proposed § 111.15(g) would require that you have adequate, readily accessible bathrooms for your employees and require that the bathrooms be kept clean and not become a potential source of contamination to your components, dietary ingredients, dietary supplements, or contact surfaces. The proposal would require that you keep your bathrooms from becoming potential sources of contamination. You would be required to keep the bathrooms in good repair at all times, provide self-closing doors, and provide doors that do not open into areas where components, dietary ingredients, dietary supplements, or contact surfaces are exposed to airborne contamination, except where you have taken other means (such as double doors or positive airflow systems) to protect against airborne contamination.

Proposed § 111.15(h) applies to hand washing facilities. The proposal would require that you provide adequate and convenient hand washing facilities that furnish running water at a suitable temperature. Proposed § 111.15(h)(1) would require that you have hand washing facilities and, where appropriate, hand sanitizing facilities at each location in your physical plant

where good hygienic practices require your employees to wash or sanitize (or to both wash and sanitize) their hands.

One comment to the ANPRM suggested that, instead of requiring employees to wash ''and/or'' sanitize their hands, we should require employees to wash ''or'' sanitize their hands.

We disagree with the comments. In some cases, it is necessary to both wash and sanitize the hands. Sanitizing which generally refers to the removal or elimination of living microorganisms, may be more effective if the hands are washed before they are sanitized, and washing, alone, will not sanitize the hands. Therefore, the proposed rule would address situations where good hygienic practices require employees to wash or sanitize their hands or to wash and sanitize their hands.

Proposed § 111.15(h)(2) and (h)(3) would require that you provide effective hand-cleaning and sanitizing preparations and air driers, sanitary towel service, or other suitable drying devices. Disposable paper towels would be an example of sanitary towel service.

One comment to the ANPRM suggested replacing ''effective hand-cleaning and sanitizing preparation'' with ''commonly available'' hand-washing and sanitizing preparations.

We disagree with the comment. The purpose behind proposed § 111.15(h)(2) is to ensure that hand-cleaning and sanitizing preparations are effective. While we have objection to the use of ''commonly available'' hand-washing and sanitizing preparations if they are ''effective,'' the effectiveness of the hand-washing and sanitizing preparation is essential to ensuring that the hand-washing and sanitizing preparation will prevent adulteration of the product.

Another comment to the ANPRM suggested that a dietary supplement CGMP rule mention paper towels as a hand drying device.

We have drafted proposed § 111.15(h)(3) to identity disposable paper towels as an example of sanitary towel service. However, under proposed § 111.15(h)(3), the paper towels must be both sanitary and disposable.

Another comment to the ANPRM suggested that paper towels used in hand-washing facilities should be made from recycled paper.

We take no position regarding the use of paper towels made from recycled paper. The proposal neither requires nor prohibits the use of paper towels made from recycled paper.

Proposed § 111.15(h)(4) would require that you provide devices or fixtures that are constructed to prevent recontamination of clean, sanitized hands. For example, if sanitized hands are necessary at a particular location, you might install hand sanitizing facilities that can be activated by foot pedals or by motion so that your employees do not have to use their hands—and, by doing so, risk contaminating their hands—to turn on the hand sanitizing equipment.

Proposed § 111.15(h)(5) would require that you have easily-understood signs and to post them throughout your physical plant to direct your employees who handle components, dietary ingredients, dietary supplements, or contact surfaces to wash and, where appropriate, sanitize their hands:

- Before they start work,
- After each absence from their duty station, and
- When their hands may have become soiled or contaminated.

Proposed § 111.15(h)(6) would require that you have trash bins that are constructed and maintained in a manner to protect against recontamination of hands and contamination of components, dietary ingredients, dietary supplements, or any contact surface. The proposal would not specify any particular type of trash bin to use.

Proposed § 111.15(i) applies to trash disposal. The proposal would require that you convey, store, and dispose of trash to minimize the development of odors; to minimize the potential for trash to attract, harbor, or become a breeding place for pests; to protect against contamination of components, dietary ingredients, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant and to control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.

Proposed § 111.15(j) would require that you assign one or more employees to supervise overall sanitation. Under the proposal, the employee or employees would have to be qualified by training and experience to develop and supervise sanitation procedures. The proposal would give you discretion in deciding how many employees you need to assign to supervise overall sanitation of your physical plant. As previously discussed, the proposed requirement does not preclude the possibility of a one-person operation. If you are a one-person operation, you would need to be qualified by training and experience to develop and perform all sanitation procedures.

We invite comment on whether written procedures for maintenance, cleaning, and sanitation should be required in a final rule. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

We invite comment on whether documentation at the time of performance of equipment, utensil, and contact surface maintenance, cleaning, and sanitation and keeping such records should be required in a final rule. This would give you a record that you would be able to consult if any questions regarding maintenance, cleaning, and sanitation of equipment used in producing the batch arise. We seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

2. What Design and Construction Requirements Apply to Your Physical Plant? (Proposed § 111.20)

Proposed § 111.20 would describe the general requirements for physical plant construction and design that are necessary to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, and holding.

Proposed § 111.20(a) would require any physical plant you use in the manufacturing, packaging, or holding of dietary ingredients or dietary supplements to be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations. You should note that proposed § 111.20(a) refers to cleaning

operations and to sanitizing operations. Although these terms appear to be similar, they are distinct in the sense that a sanitizing operation usually produces a sterile (free of living microorganisms) environment whereas a cleaning operation may not. To illustrate the difference, if you wipe a contact surface with a wet cloth to remove any components or dietary ingredients, you would have engaged in a cleaning operation. The contact surface is free of noticeable debris, but it might still contain microorganisms. In contrast, if you used a disinfectant on the contact surface in order to eliminate any possible microorganisms on that surface, you would have engaged in a sanitizing operation.

Size, construction, and design of a physical plant are important to manufacturing, packaging, and holding dietary ingredients and dietary supplements that are not adulterated because they can help you identify and eliminate possible sources of contamination that result in or may lead to adulteration. For example, condensation can occur on water pipes. If these pipes are exposed and run above a contact surface, condensation from those pipes may fall onto the contact surface and adulterate your dietary ingredients or dietary supplements. So, if you design your physical plant to eliminate exposed pipes or to shield your contact surfaces from condensation, you would eliminate a possible source of adulteration.

As another example, you might find it more practical to clean certain floors in your physical plant by spraying them with water. Obviously, a floor design that uses floor drains would facilitate the cleaning of those floors.

Proposed § 111.20(b) would require your physical plant to 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, dietary ingredients, and dietary supplements during manufacturing, packaging, or holding. Adequate space for the orderly placement of equipment and holding of materials is important because it can directly affect your ability to maintain, clean, or sanitize your equipment or physical plant effectively. For example, assume that your manufacturing operation involves the use of a large mixer. However, the mixer is installed in a small room which makes it difficult to open the mixer fully. This may make it difficult for you to maintain and clean the mixer properly and, as a result, may increase the possibility that residues in the mixer will contaminate the next batch of ingredients that go into the mixer.

Proposed § 111.20(c) would require your physical plant to permit the use of proper precautions to reduce the potential for mixups or contamination of components, dietary ingredients, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. The proposal would require the physical plant to have, and require that you 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, dietary ingredients, and dietary supplements during specific operations. The specific operations would be listed at proposed § 111.20(c)(1) through (c)(7) and are as follows:

- Receiving, identifying, holding, and withholding from use, components, dietary ingredients, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, or holding of dietary ingredients and dietary supplements;
- Separating, as necessary, components, dietary ingredients, dietary supplements, packaging, and labels that are to be used from components, dietary ingredients, dietary supplements, packaging, or labels that are awaiting material review and disposition decision, reprocessing, or are awaiting disposal after rejection;
- Separating the manufacturing, packaging, and holding of different product types, including, but not limited to, different types of dietary ingredients, dietary supplements, and other foods, cosmetics, and pharmaceutical products;
- Performing laboratory analyses and holding laboratory supplies and samples;
- Cleaning and sanitizing contact surfaces;
- Packaging and label operations; and
- Holding dietary ingredients or dietary supplements.

The proposal would not specify the types of precautions your physical plant must have to reduce the potential for mixups or contamination. The precautions may depend on your physical plant and the products you make. For example, depending on your physical plant's size and layout, you may be able to receive components and dietary ingredients at one location, hold them in another location and store rejected components and dietary ingredients in yet another location. However, if your physical plant does not allow for physically separate areas, you would have to develop an alternative approach for segregating components, dietary ingredients, and dietary supplements at points when they are received, stored, and rejected.

Proposed § 111.20(d) would require that your physical plant be designed and constructed in a manner that prevents contamination of components, dietary ingredients, dietary supplements, or contact surfaces. The proposal would require that the design and construction include floors, walls, and ceilings that are of smooth and hard surfaces that may be adequately cleaned and kept clean and in good repair. Smooth, hard surfaces are necessary because they are easier to clean and sanitize than those surfaces that are not smooth and hard. The proposal also would require that you use fixtures, ducts, and pipes that do not contaminate components, dietary ingredients, dietary supplements, or contact surfaces by dripping or condensate. Condensation may contain microorganisms or contaminants that can contaminate your components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.20(d) also would require your physical plant's design and construction to:

- Use 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 ingredients, dietary supplements or contact surfaces. Adequate ventilation or environmental control equipment is a necessary part of your physical plant's design and construction because some contaminants and microorganisms may be airborne, so a failure to provide adequate ventilation will increase your chances of airborne contamination. In addition, some potentially harmful gases (such as carbon monoxide and carbon dioxide) are colorless and odorless, so it is important to have a ventilation or environmental control system that minimizes odors and vapors;
- Use fans and other air-blowing 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;
- Use equipment to control temperature and humidity. For example, high temperatures may stimulate

reproduction of microorganisms and pests, and these microorganisms and pests may, in turn, contaminate your components, dietary ingredients, dietary supplements, and contact surfaces; and

• Include 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 ingredients, dietary supplements, or contact surfaces with clothing or personal contact. For example, your employees will perform their duties more efficiently and more effectively if they have sufficient space to perform those duties. The clothing worn by your employees will be less likely to be a source of contamination if there is sufficient space between your employees and your components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.20(e) would require your physical plant to provide adequate light in all areas where components, dietary ingredients, or dietary supplements are examined, processed, or held and in all areas where contact surfaces are cleaned. Proposed § 111.20(e) also would require that you provide adequate lighting in hand washing areas, dressing and locker rooms, and bathrooms. Inadequate lighting in areas where components, dietary ingredients, or dietary supplements are examined, processed, or held may make it difficult to examine a component or read a label; as a result, incorrect ingredients may be used in a dietary supplement. Adequate lighting also is important in areas where contact surfaces are cleaned to ensure that the contact surfaces have been cleaned properly. Adequate lighting is important in hand-washing areas, dressing and locker rooms to ensure that personal cleanliness is maintained in accordance with proposed § 111.10(b).

Proposed § 111.20(f) would require your physical plant to use safety-type light bulbs, fixtures, skylights, or other glass that is suspended over exposed components, dietary ingredients, or dietary supplements in any step of preparation, unless otherwise constructed in a manner that will protect against contamination in case of glass breakage. These precautions are necessary because glass shards can be very small and difficult to see, and some lights may spread their contents if they burst or explode. So, to protect your components, dietary ingredients, and dietary supplements, the proposal would require your physical plant to take precautions concerning your lighting and other suspended glass.

Proposed § 111.20(g) would require that your physical plant provide protection by any effective means against contamination of components, dietary ingredients, and dietary supplements in bulk fermentation vessels. The proposal describes some means to consider, such as using protective coverings, placement in areas where you can eliminate harborages for pests over and around vessels, placing bulk fermentation vessels in areas where you can check regularly for pests, pest infestation, filth, or other extraneous material, and using skimming equipment. You must protect components, dietary ingredients, and dietary supplements held in bulk fermentation vessels because, if the contents of a bulk fermentation vessel are contaminated, those contaminated contents may be used to make many dietary ingredients or dietary supplements that, as a result, would be adulterated.

Proposed § 111.20(h) would require your physical plant to include adequate screening or other protection against pests, where necessary. This provision would be one measure to exclude certain pests from the physical plant that also may assist you in complying with proposed § 111.15(c). As we explained earlier in the discussion of proposed § 111.15(c), pests are a potential source of contamination because they may carry microorganisms, shed hair or feathers, leave droppings, or carry filth or dirt into your physical plant.

*D. Equipment and Utensils (Proposed Subpart D)*

Proposed subpart D consists of two provisions. These proposed provisions consist of general requirements for equipment and utensils and for automatic equipment, including computerized systems, hardware, and software.

1. What Requirements Apply to the Equipment and Utensils You Use? (Proposed § 111.25)

Proposed § 111.25 would establish general requirements pertaining to equipment design, construction, and sanitation. For example, proposed § 111.25(a)(1) would require that you use equipment and utensils of appropriate design, construction, and workmanship that would enable them to be suitable for their intended use, adequately cleaned, and properly maintained. The equipment and utensils covered under the proposal would include, but not be limited to:

• Equipment used to hold or convey;
• Equipment used to measure;
• Equipment using compressed air or gas;
• Equipment used to carry out processes in closed pipes and vessels; and
• Equipment used in automatic, mechanical, or electronic systems.

To show how proposed § 111.25(a)(1) might apply, assume that you use a mixer to blend powdered ingredients. If the mixer blade is too small, it might not mix the ingredients properly or thoroughly, and the resulting batches might be adulterated if the ingredients are not provided at the required levels throughout the batch. In this example, the mixer was not suited for its intended use. As another example, if your manufacturing equipment is so complex or designed in a way that makes cleaning difficult, any unclean surfaces on that equipment could become a source of contamination in the future. In this case, the equipment was not adequately cleaned and properly maintained or, alternatively, was not of appropriate design for its intended uses.

Proposed § 111.25(a)(2) would require that you use equipment and utensils of appropriate design and construction whose use will not result in the contamination of your components, dietary ingredients, or dietary supplements with lubricants, fuel, coolants, metal or glass fragments, filth or other extraneous material, contaminated water, or any other contaminants.

Proposed § 111.25(a)(3) would require your equipment and utensils to be:

• Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces;
• Corrosion-resistant if the equipment or utensils contact components, dietary ingredients, or dietary supplements;
• Made of nontoxic materials;
• Designed and constructed to withstand the environment of their intended use, the action of components, dietary ingredients, or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and
• Maintained to protect components, dietary ingredients, and dietary supplements from being contaminated by any source.

Deteriorating equipment can be a source of contamination. For example, repeated contact between metal surfaces in a grinding or tableting machine can result in metal fragments that can contaminate your dietary ingredients or dietary supplements. So, your equipment and utensils must be designed and constructed to withstand the environment of their intended use and you must maintain your equipment

and utensils to guard against contamination.

Proposed § 111.25(a)(4) would require your equipment and utensils to have seams that are smoothly bonded or maintained to minimize accumulation of component, dietary ingredient, or dietary supplement particles, dirt, filth, organic material, or any other extraneous material or contaminants. We are proposing this requirement because equipment and utensils containing breaks, pits, cuts, or grooves can be difficult to clean, and the pores or crevices in those breaks, pits, cuts, or grooves can become a breeding ground for microorganisms and insulate them from cleaning and sanitizing agents.

Proposed § 111.25(a)(5) would require freezers and cold storage compartments that hold components, dietary ingredients, or dietary supplements to be fitted with accurate thermometers or other temperature-measuring or temperature-recording devices and would recommend automatic devices for regulating temperature or for sounding an alarm to indicate significant temperature changes in a manual operation. These devices are necessary to ensure that you are able to monitor the temperatures where you hold your components, dietary ingredients, or dietary supplements and to indicate whether they were held at appropriate temperatures to minimize the growth of pathogens and to prevent deterioration.

While we patterned proposed § 111.25(a)(5) after a provision in the food CGMPs (§ 110.40(e)), we invite comment on whether we should require specific target temperatures for dietary ingredients or dietary supplements held in freezers or cold storage, and if so, what those temperatures should be and why.

Proposed § 111.25(a)(6) would require instruments or controls used in the manufacturing, packaging, or holding of a dietary ingredient or dietary supplement to be accurate and precise, adequately maintained, and adequate in number for their designated uses. By using the words, ''accurate and precise,'' we mean that the instruments or controls must be accurate—the recorded measurements are equal to the true value of the thing being measured—and precise—individual measurements should be close to each other when made under the same conditions. For example, if the temperature inside a particular piece of equipment is 100 °F, and your thermometer for that piece of equipment reads a temperature of 100 °F, the thermometer is accurate. If multiple temperature readings for that thermometer ranged from 99.7 °F to 100.4 °F, and the variation in temperature was not significant statistically, you could say the thermometer is precise. The proposed requirement identifies examples of such instruments and controls, such as instruments or controls you use to measure, regulate, or record:

- Temperatures;
- pH;
- Water activity; or
- Other conditions that control or prevent the growth of microorganisms or other contamination.

Instruments or controls that affect the environment, such as instruments that regulate temperature, pH, and water activity, are important because environmental factors can influence microorganism growth and deterioration. For example, changes in water activity ($a_w$) can have a dramatic impact on microorganism growth. A population of *Salmonella typhimurium* is reduced tenfold in 0.18 minutes at 60 °C if the $a_w$ for the suspending medium is 0.995. If the $a_w$ is 0.94, it takes 4.3 minutes (or nearly 24 times as long) at 60 °C to achieve the same tenfold reduction (Ref. 58).

Adequate maintenance is an important part of proposed § 111.25(a)(6). If you fail to properly maintain your instruments and controls, they may produce unreliable readings and contribute towards the contamination and adulteration of your dietary ingredients and dietary supplements. For example, assume that you refrigerate a particular dietary ingredient to prevent microorganism growth. If your refrigerator gives you the wrong temperature readings so that the actual temperature inside your refrigerator is too high, you may be unaware of microorganism growth that has occurred on your dietary ingredient. Similarly, if the actual temperature inside your refrigerator is too low so that you unintentionally froze the dietary ingredient, the freezing process may have produced a chemical change in your dietary ingredient that will cause it to be out of specification.

Note, too, that the proposal also would require that your instruments and controls be adequate in number for their designated uses. For example, if the temperature of a large piece of equipment needs to be monitored, several temperature-indicating devices may be needed to accurately monitor the temperature in all parts of the equipment.

A comment to the ANPRM objected to requiring all instruments and controls used in all aspects of dietary supplement manufacturing be accurate. The comment said such a requirement would imply strongly a need for validation, but that validation is a standard applicable to drug CGMPs, but not to food CGMPs. The comment said that a dietary supplement CGMP rule should not require validation of instruments and controls.

We disagree with the comment's objection to requiring all instrument and controls be accurate because, as we stated earlier, inaccurate instruments and controls may generate inaccurate readings, and those readings may adulterate your dietary ingredients and dietary supplements. We believe that all instruments and controls used in the manufacture, packaging, and holding of dietary ingredients and dietary supplements be accurate and precise, adequately maintained, and adequate in number for their designated uses.

We further disagree that the principles of validation are applicable to drugs, but not to foods. We stated in a previous FDA publication (Ref. 59) that the ''computerized system used to control critical functions in food processing should be validated in its entirety.'' We have no basis to conclude that validation of instruments and controls is a standard applicable to drugs and not to foods, nor did the comment provide a reason for its assertion that validation does not apply to foods. We invite comment in this proposal on whether we should include requirements in a final rule, that would address the same or similar concerns that the principles of validation would address. We also invite comment on whether there are other procedures that we should include in a final rule.

Proposed § 111.25(a)(7) would require compressed air and other gases that are introduced into or onto a component, dietary ingredient, dietary supplement, or contact surface or that are used to clean contact surfaces to be treated in a way so that they do not contaminate the component, dietary ingredient, dietary supplement or contact surface. Air or other gases that are not properly treated and filtered, or air that is not of the proper purity, can introduce contaminants into the dietary supplement product and adulterate it. Also, compressed gases can be contaminated with oil from the equipment (such as an air compressor) or with filth or microbiological contaminants from the compression, storage, or distribution equipment. So, if left untreated, the compressed air can deposit those contaminants onto your components, dietary ingredients, dietary supplements, and contact surfaces. Filtration at the air intake and after compression, storage, and distribution may be an effective means of reducing

the risk that such contaminants will enter the compressed air or other gases.

Proposed § 111.25(b)(1) would require that you calibrate your instruments and controls that you use in manufacturing or testing components, dietary ingredients, or dietary supplements. Proposed § 111.25(b)(2) would require that you calibrate before you first use the instruments and controls and either as specified in writing by the manufacturer of the instrument and control or at routine intervals or as otherwise necessary to ensure their accuracy and precision. Calibrating instruments and controls will ensure that they are accurate and precise and that the instrument or control readings are ''true values.'' We invite comment on whether we should require, in a final rule, that you establish and follow a written procedure for calibrating instruments and controls, and whether there are other procedures, that we should consider including in a final rule. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

Proposed § 111.25(c) would require that you must establish a written procedure for calibrating instruments and controls you use in manufacturing or testing a component, dietary ingredient, or dietary supplement and document that the written procedure was followed each time a calibration was performed or that you must document, at the time of performance, that the instrument and control calibration established in accordance with this section was performed. The proposed calibration requirement gives you discretion in deciding whether to establish and follow a written calibration procedure. If you establish a written procedure for calibrating instruments and controls, you must document, at the time of calibration performance, that the written procedure was performed. If you do not establish a written calibration procedure then you must document, at the time of performance, that the calibration established accordance with this section was performed. You must identify the following for calibrating instruments and controls in any written procedure or at the time of performance:

- The instrument or control calibrated;
- The date of calibration;
- The reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy. A certification of accuracy usually accompanies a standard reference material and often is valid for a specific period of time, but the supplier of the reference standard may recertify the standard's accuracy. The recertification typically involves testing by the supplier to verify that the material maintains accuracy as a testing reference. This information also may help you trace the source of a problem, if one arises, in your dietary ingredients or dietary supplements. For example, if consumers report an adverse event with a batch of dietary supplements, records containing a certification of accuracy of the reference standards used and a history of their recertification would help you determine if the problem resulted from using an inaccurate reference standard to calibrate your instruments;
- The calibration method used including appropriate limits for accuracy and precision of instruments and controls when calibrating;
- The calibration reading or readings found;
- The recalibration method used if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and
- The initials of the person who performed the calibration.

These records will enable you to determine whether the calibration schedule can maintain the accuracy of your instruments and controls, and will also provide information on when and how the instruments and controls were calibrated in case a problem arises with a batch of dietary ingredients or dietary supplements. If you examine these records over time, you also will be able to see how precise your instruments and controls are and to make any necessary adjustments or repairs. For example, if your records show that a scale gives a particular reading for a standard reference weight in January, but then shows a different reading in June for the same standard reference weight, you may need to adjust, repair, or even replace your scale.

In fact, proposed § 111.25(d) would require that you repair or replace instruments and controls that cannot be adjusted to agree with the reference standard. You should not trust any instrument or control that cannot be adjusted to agree with a reference standard because an inaccurate measurement or reading may result in an adulterated dietary ingredient or dietary supplement. Again, to use a scale as an example, if you have a scale that you cannot adjust to read the correct weight, using that scale to weigh a dietary ingredient to be added to a particular mix would cause you to add either too much or too little of the dietary ingredient into your mix, thus throwing your mix out of specification. So, proposed § 111.25(d) would require that you repair or replace that scale.

Proposed § 111.25(e) applies to maintenance and sanitation. The word ''maintenance,'' in this provision, means the act of keeping your equipment and utensils in working order as recommended by their manufacturer. Proposed § 111.25(e)(1) would require that you maintain, clean, and sanitize, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, or hold components, dietary ingredients, or dietary supplements and to take apart your equipment and utensils as necessary for thorough maintenance, cleaning, and sanitizing. Obviously, if you fail to keep your equipment, utensils, and contact surfaces clean, you risk contaminating them with microorganisms and other contaminants and risk transferring those microorganisms or other contaminants to anything that touches the equipment, utensils, and contact surfaces.

Proposed § 111.25(e)(2) would require that you ensure that all contact surfaces used for manufacturing or holding low-moisture components, dietary ingredients, or dietary supplements are in a dry and sanitary condition at the time of their use. If the surfaces are wet-cleaned, you must sanitize them, when

necessary, and allow them to dry thoroughly before you use them again.

Thoroughly drying equipment before it is used for manufacturing or holding dry dietary products is essential to ensure that the equipment will not change the composition of the dry product. For example, if moisture is left on equipment, the moisture will become a part of the product and may change the composition of the product. Moist surfaces can also promote microorganism growth, and microorganisms can adulterate your components, dietary ingredients, or dietary supplements.

Proposed § 111.25(e)(3) would apply if you use wet processing during manufacturing. Under the proposal, you would have to clean and sanitize all contact surfaces as necessary to protect against the introduction of microorganisms into components, dietary ingredients, or dietary supplements. Proposed § 111.25(e)(3) also would require that, 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 become contaminated. If you use contact surfaces in a continuous production operation or in back-to-back operations involving different batches of the same dietary ingredient or dietary supplement, the proposal would require that you clean and sanitize the contact surfaces as necessary.

Proposed § 111.25(e)(4) would complement proposed § 111.25(e)(2) and (e)(3) by requiring that you clean, as frequently as necessary, surfaces that do not touch components, dietary ingredients, or dietary supplements to protect against contamination. 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, dietary ingredients, 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 ingredients, dietary supplements, and contact surfaces.

Proposed § 111.25(e)(5) would establish requirements for single-service articles, such as utensils intended for one-time use, paper cups, and paper towels. Proposed § 111.25(e)(5) would require these articles to be stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or any contact surface. For example, you would not place a paper towel dispenser over a contact surface because persons reaching for those paper towels might drip contaminated water or other fluids onto the contact surface. Inadvertent reuse of a single-service article also could lead to contamination, so disposing of single-service articles is an important element in proposed § 111.25(e)(5).

Proposed § 111.25(e)(6) would require your cleaning compounds and sanitizing agents to be adequate for their intended uses and safe under their conditions of use. An adequate cleaning compound is one that will lower the surface tension of water so that spills can be lifted and flushed away (Ref. 60). Ordinary soap has a limited ability to solubilize fats, oils, and proteins. Inorganic alkaline detergents can dissolve food solids, such as fats and proteins, but mineral deposits will frequently require the use of acid cleaners (Ref. 60). Proposed § 111.25(e)(6) would not prescribe any particular cleaning compound. Instead, you may select cleaning compounds that are suited to your particular needs. An adequate sanitizing agent is one that has a bactericidal effect on the types of microorganisms normally present in the physical plant environment and is safe, chemically stable, and convenient for use. However, sanitizing agents can achieve their intended effect only after they are applied to a surface that has been thoroughly cleaned, and if they are applied at a proper concentration (Ref. 61).

Proposed § 111.25(e)(7) would require that you store cleaned and sanitized portable equipment and utensils that have a contact surface in locations and in a manner that protect them from contamination. This requirement is necessary to ensure that your portable equipment remains clean and sanitized until used; otherwise, if the contact surfaces on the portable equipment or utensils become contaminated, they could lead to adulteration of your dietary ingredients or dietary supplements.

We invite comment on whether we should require, in a final rule, that you establish and follow a written procedure for maintenance, cleaning, and sanitizing. Further, we invite comment on whether we should require that the person who performs the maintenance, cleaning, and sanitizing described in this section document, at the time of performance that the maintenance, cleaning, and sanitizing were performed. Those procedures may be helpful to inform you that equipment is being maintained, cleaned, and sanitized regularly and as frequently as is necessary based on the actual use, as opposed to the planned use, of the equipment. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

As discussed later, proposed § 111.50(c)(4) would require that you document, in the batch production record, the date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used to producing the batch. Records that document the batch or lot number of each batch or lot of dietary ingredients or dietary supplements processed using a particular piece of equipment or a particular utensil between equipment startup and shutdown for maintenance, cleaning, and sanitizing will allow you to identify all dietary ingredients or dietary supplements that may have been manufactured or packaged with a specific piece of equipment or utensil if you later discover that the equipment or utensil was improperly maintained, cleaned, or sanitized.

Proposed § 111.25(f) would require that you keep calibration records as required by this section in accordance with the recordkeeping requirements in proposed § 111.125. Such records will verify for you and the agency that calibrations are performed. More importantly, these records will help you ensure that all calibrations are performed. If problems do occur with the production of a product, these records will help you determine whether those problems are associated with faulty calibrations. These records will help you determine which batches were produced under these conditions. Further, these records will help you train employees or adjust the calibration schedule as needed to avoid further problems.

2. What Requirements Apply to Automatic, Mechanical, or Electronic Equipment? (Proposed § 111.30)

Manufacturers of dietary ingredients and dietary supplements often rely on automatic, mechanical, and electronic

equipment in production. Automated equipment is often used to ensure proper formulation, mixing, and processing or to test a batch of dietary ingredient or dietary supplement. Such automated equipment frequently consists of a computer or system of computers that control many or all stages of production, inprocess sampling, and testing. It is important that such systems and equipment function as expected to ensure that the dietary ingredient or dietary supplement contains the correct ingredients in the appropriate amounts and is manufactured according to these CGMP proposed requirements, and thus, is not adulterated under section 402(g) of the act.

Proposed § 111.30 sets forth requirements for automatic, mechanical, or electronic equipment. These types of equipment include, for example, mechanical equipment such as a scale used to weigh bulk components and electronic equipment such as a computerized blending machine.

Proposed § 111.30(a) would allow you to use automatic, mechanical or electronic equipment to manufacture, package, label, and hold a dietary ingredient or dietary supplement. Thus, the proposal would let you decide what type of equipment meets your needs. Proposed § 111.30(a)(1) would require that you must design or select equipment to ensure that dietary ingredient or dietary supplement specifications are consistently achieved. Equipment used in dietary ingredient or dietary supplement manufacturing, packaging, and label operations must be, for example, of an appropriate size and installed properly in order to produce an unadulterated product. If not designed or installed properly, the equipment can lead to a variety of problems. For example, a mixer for the blending of powdered ingredients will not properly perform its function if the blade is too small relative to the size of the mixer or not properly placed inside of the mixer. Such a mixer may produce an adulterated product because the dietary supplement, for example, is not of uniform composition and therefore would not be able to meet the specifications for purity, quality, strength, or composition in the final product. Thus, equipment design and selection is critical to ensure that you manufacture an unadulterated dietary ingredient or dietary supplement.

Proposed § 111.30(a)(2) would require that you determine the suitability of your equipment. The equipment that you use must be capable of operating satisfactorily within the operating limits required by the process. The equipment must function as intended. 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 the system, tested under conditions that reflect actual conditions of use, and properly maintained to ensure that they continue to function as expected during their lifetime.

Moreover, the incorporation of software into the operation of automatic equipment has not only increased the complexity of such equipment but also has 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, proposed § 111.30(a) would require that you exercise appropriate controls over systems and, in particular, over the software used in the systems.

Proposed § 111.30(b) would require, for any automatic, mechanical, or electronic equipment that you use, that you must:

- Routinely calibrate, inspect, or check to ensure proper performance.
- Make and keep written records of equipment calibrations, inspections, or checks;
- Establish and use appropriate controls to ensure that your quality control unit approves changes in master manufacturing record, batch control records, packaging operations and label operations, or changes related to the equipment that you use and that only authorized personnel institute the changes;
- Establish and use appropriate controls to ensure that the equipment functions in accordance with its intended use and have your quality control unit approve these controls; and
- Make and keep backup file(s) of software programs and of data entered into your computer system. Your backup file may be a hard copy of data you have entered, diskettes, tapes, microfilm, or compact disks but must be an exact and complete record of the data you entered. We also propose to require that you keep your backup software programs and data secure from alterations, inadvertent erasures, or loss. In this way, you have a record of changes to your software program and of your current software program used in manufacturing. This information is important to both identify any production errors or discrepancies and to make necessary corrections. Such records will allow you to troubleshoot and to operate these systems with a minimum of interruption when problems occur because the records will include a copy of all software used and a backup file of data entered into the computer or related system which can be used to reload the system. The records also will provide information that you can use in trying to determine why a problem with the system is occurring or why the system is not producing a dietary ingredient or dietary supplement that complies with your specifications for the product.

Appropriate controls that you establish and use for automated measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions will minimize the potential for growth of microorganisms, for contamination, or for adding too much or too little of a dietary ingredient. Observations, inspections, and checks of the equipment will help you to determine if critical factors such as revolutions per minute, temperatures, pressures, process times, and automatic documentation are being controlled by the system. Under proposed § 111.30(b), examples of controls to ensure that the equipment functions in accordance with its intended use include:

- Determining the extent and frequency of calibration, inspections and checks to ensure proper performance;
- Determining and using predetermined action plans when an alarm sounds indicating an out-of-limits situation or malfunction;
- Checking in-put and out-put on a sufficient basis to provide a high degree of assurance that input and output is accurate;
- Comparing manual calculations of data with the automated calculations on a sufficient basis to provide a high degree of assurance that the automated calculations are accurate; and
- Determining the adequacy of automated cleaning and residue elimination.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures for the calibration, inspection, and checking of automatic equipment. In addition, we invite comment on whether there are procedures, other than those mentioned, that we should include in a final rule. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

For computerized equipment, you should note that we already have issued guidance documents that may give you some helpful information. The guidance documents are: ''FDA Guide to Inspections of Computerized Systems in the Food Processing Industry'' (Ref. 59), and a ''Guide to Inspections of Computerized Systems in Drug Processing'' (Ref. 62). Although we did not draft these guidance documents for dietary ingredient and dietary supplement firms, they still provide important advice on establishing and using computerized systems in dietary supplement manufacturing operations. Given the broad range in sophistication, complexity, and computerization in manufacturing equipment, we invite comments on whether we should regulate computerized systems separately from other automatic equipment.

Although we are not proposing verification requirements in this proposed rule, we are seeking comment on whether such verification should be included in a final rule. Verification would be intended to 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 be intended to show you whether your automatic, mechanical, or electronic processes will consistently operate as they should.

We believe, in general, that scientific knowledge and industry experience have defined the basic elements of a sound verification system to include; determining whether the capacity of the hardware matches its assigned function; identifying and considering operational limits in establishing production procedures; determining whether the software matches the assigned operational function; testing simulated production conditions including ''worst case'' conditions; repeating tests enough times to assure a reasonable measure of consistent reproducible results; documenting the verification program; and initiating reverification when significant changes are made to the system or when errors are noted.

Although verification steps would vary according to the nature of the dietary supplement and the complexity of the process, the basic elements of a verification system would be generally applicable to all dietary ingredients and dietary supplements. The primary benefit of a verification system would be to provide a foundation for building a comprehensive approach to ensure that the equipment performs in a predetermined way, but verification could impose additional costs on manufacturers.

We invite comment on whether automatic, mechanical, and electronic equipment verification and reverification elements that we have discussed should be done, should be included in the final rule as requirements, which would include requirements to document the verification steps. We invite comment on whether we should regulate computerized systems separately from other automatic equipment. We seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

### *E. Production and Process Controls (Proposed Subpart E)*

Proposed subpart E contains production and process controls to help ensure that you have controls covering all manufacturing, packaging, label, and holding operations, and that those controls will prevent adulteration of your dietary ingredient or dietary supplement. We propose to establish a framework in which decisions about producing a dietary ingredient or dietary supplement are left to you, but that charges you with incorporating into your production process, measures that are designed to ensure that the dietary ingredient or dietary supplement is manufactured in a manner that will prevent adulteration and misbranding.

Dietary ingredient and dietary supplement manufacturing requires technical knowledge and skill (*e.g.*, in research and development, production equipment and procedures, and analytical equipment and methodology) that a vast majority of companies in the food processing industry do not have. A dietary ingredient or dietary supplement manufacturer must maintain constant control because a seemingly innocuous change in the formulation or preparation method or in exposure to an unanticipated environmental condition could create a health hazard. Earlier, in section I.E of this document in our discussion of ''FDA's Decision to Propose a Rule,'' we cite several examples of problems arising from poorly controlled manufacturing practices. For example, we cite problems of dietary ingredient misidentification; super- and subpotent dietary supplements; and contamination including toxic substances, microorganisms of public health significance, and heavy metals. Thus, we believe that using a production and inprocess control system covering all stages of processing is necessary to insure that the dietary ingredient or dietary supplement is manufactured in a manner that will prevent adulteration.

#### 1. What Production and Process Controls Must You Use? (Proposed § 111.35)

Proposed § 111.35(a) would require that you implement a system of production and inprocess controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary ingredients and dietary supplements.

Proposed § 111.35(b) would require that your production and inprocess control system must be designed to ensure that you manufacture, package, or hold dietary ingredients or dietary

supplements in a manner that will prevent their adulteration. The proposal would require that your production and inprocess control system must include all requirements of this subpart and also would require your quality control unit to review and approve the production and inprocess control system. We believe that requiring a production and inprocess control system is necessary to provide consistency in producing different batches of dietary ingredients or dietary supplements and to facilitate preparing each batch.

Proposed § 111.35(c) would require that you use your quality control unit in your manufacturing, packaging, and label operations to ensure that these operations are performed in a manner that prevents adulteration and to ensure that the dietary ingredient or dietary supplement meets specifications for identity, purity, quality, strength, and composition.

Proposed § 111.35(d) establishes requirements for any substance that may be used in a dietary ingredient or a dietary supplement. This section would require that any substance that is used be a ''dietary ingredient'' within the meaning of that term in section 201(ff) of the act, or, if not included with the meaning of that term, must meet the applicable statutory and regulatory requirements under section 409 of the act, or section 721 of the act (21 U.S.C. 379e) if a color additive, to ensure that the substance is safe and lawful for use in a dietary ingredient or a dietary supplement.

A ''dietary ingredient'' within the meaning of section 201(ff) of the act that is in, or intended for use in, a dietary supplement is exempt from the definition of ''food additive'' in section 201(s). Such ''dietary ingredients'' are not subject to the premarket approval standard for food additives under section 409 of the act. However, under section 402(f)(1) of the act, in order for a dietary ingredient or a dietary supplement not to be deemed adulterated, substances that are ''dietary ingredients'' that are used in the manufacture of a dietary ingredient or a dietary supplement must not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling or, if no such labeling, under ordinary conditions of use. In addition, there must be adequate information to provide reasonable assurance that a new dietary ingredient does not present a significant or unreasonable risk of illness or injury. Further, under section 402(f)(1) of the act, dietary ingredients must not be poisonous or deleterious substances within the meaning of section 402(a)(1) of the act. Thus, manufacturers have a responsibility to ensure that the dietary ingredients and dietary supplements that they produce are not adulterated under section 402(f) of the act.

However, certain substances are not ''dietary ingredients'' within the meaning of section 201(ff) of the act, and thus, are not exempt under section 201(s) from regulation as a food additive under section 409 of the act. Such substances include components that are added to provide certain technical effects to the dietary supplement, such as disintegration, lubrication, or binding. In addition, such substances may include color additives that are used or intended for use to impart color to the dietary ingredient or dietary supplement. Color additives are exempt from the definition of ''food additive'' under section 201(s)(3) of the act and subject to approval and listing under section 721 of the act.

Proposed § 111.35(d) would require that any substance, other than a ''dietary ingredient,'' 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 the dietary ingredient or dietary supplement, must be:

- Authorized for use as a food additive under section 409 of the act, or
- Authorized by a prior sanction consistent with 21 CFR 170.3(l), or
- If used as a color additive, subject to a listing that, by the terms of that listing, includes the use in a dietary supplement, or
- Generally recognized as safe (GRAS) for use in a dietary ingredient or dietary supplement. Any claim that a substance is GRAS, other than a dietary ingredient within the meaning of section 201(ff) of the act, 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 ingredient or dietary supplement, and
- Must comply with all other applicable statutory and regulatory requirements under the act.

Thus, if a color additive is used in a dietary ingredient or dietary supplement, it must be listed in Title 21 of the Code of Federal Regulations (CFR) for use in food and the listing must, by its terms, include such use in a dietary supplement. If the substance is not a color additive, it must be safe under other relevant sections of the act. Relevant considerations about the safety of a substance that may be used as an ingredient (other than a ''dietary ingredient'' under section 201(ff) of the act) in a dietary ingredient or a dietary supplement would include the amounts of the substance that likely would be ingested, based on the amounts recommended or suggested in the label, or under ordinary conditions of use. Such a use may present concerns about the safety of exposure to such ingredient, based on the chronic use suggested or reasonably expected. Therefore, it is incumbent on the manufacturer to use ''non-dietary ingredients,'' that are safe and lawful under applicable sections of the act for such use.

As stated previously, ingredients used in dietary ingredients or dietary supplements, other than color additives, are required to be approved for use as a food additive unless excepted from the definition of a food additive under section 201(s) of the act. For example, we approved the use of sucralose as a general purpose sweetener in food, which would include its use in a dietary ingredient or dietary supplement (64 FR 43908, August 12, 1999). Some other current food additive listings that would include uses in certain types of dietary supplements include, ethyl cellulose (21 CFR 172.868) as a component of protective coatings for vitamin and mineral tablets, and hydroxypropyl cellulose (21 CFR 172.870) as a binder and disintegrator in dietary supplement vitamin or mineral tablets or wafers. If you have questions about the regulatory status of any substances that you want to use in a dietary ingredient or a dietary supplement, you are encouraged to contact CFSAN's Office of Food Additive Safety.

We recognize that some ingredients may not be subject to section 409 of the act, food additive approval, because they are GRAS substances. For those substances that are GRAS, proposed § 111.35(d)(4) would require the manufacturer to have documentation for the basis for why such a substance, that is not a ''dietary ingredient'' within the meaning of section 201(ff) of the act, is approved for use or is GRAS for use in a dietary ingredient or dietary supplement.

The statute, under section 402(g)(2) of the act, provides that the Secretary may by regulation prescribe good manufacturing practices for dietary supplements. If the good manufacturing practices are not met, the dietary ingredient or dietary supplement would be adulterated under section 402(g) of the act. Under proposed § 111.35(d), substances that are not ''dietary ingredients'' that are used in dietary ingredients and dietary supplements must be safe and lawful to comply with CGMPs for such products. Thus, these

nondietary ingredient substances must be subject to a food additive listing, authorized by a prior sanction, included with the terms of a color additive listing, or listed as GRAS for such use in 21 CFR part 182 or affirmed as GRAS for such use in 21 CFR part 184. Alternatively, you can meet the requirements of § 111.35(d) by a showing that the substance is GRAS within the meaning of § 170.30 (21 CFR 170.30).

Proposed § 111.35(d)(4) would require that you have information in your files that would substantiate the GRAS status of any nondietary ingredient substance that is not otherwise the subject of a food additive approval, prior sanction, or color additive listing. We believe that, to implement the act in a way to ensure that the statutory goals are achieved; that is, to ensure that the manufacturer has the relevant information to ensure that any asserted GRAS ingredient is, in fact, GRAS, it is appropriate to require that you maintain, in your files, the basis for why the nondietary substance you assert is GRAS that you use in a dietary ingredient or dietary supplement is, in fact, GRAS. You must not use unsafe ingredients in your products. Therefore, you must have information on ingredients that you intend to use in a dietary ingredient or dietary supplement to demonstrate that such ingredient is safe. Otherwise, as a responsible manufacturer, you would not use the ingredient in your product.

Therefore, under proposed § 111.35(d)(4), for any claim that a nondietary ingredient in a dietary supplement is GRAS, you must support such claim with a cite to a FDA regulation or an explanation for why there is general recognition of the safety of the use of the substance in a dietary ingredient or dietary supplement. If such claim is based on general recognition of safety based on scientific procedures, the explanation would be based on evidence that demonstrates that there is common knowledge about the safety of the substance throughout the scientific community knowledgeable about the safety of such substance. Under § 170.30(c)(1), if a substance is GRAS based on common use in food prior to January 1, 1958, this determination must be based solely on food use of the substance before January 1, 1958, and ordinarily must be based upon generally available data and information. Thus, GRAS based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. If you wish to use an ingredient based solely on food use of the substance prior to January 1, 1958, you would need to support a claim that the ingredient is GRAS with an explanation of the basis for why the ingredient was in common use in a dietary ingredient or a dietary supplement prior to January 1, 1958, and why that use provides the basis for general recognition of the safety of the substance.

We will view any ingredient, that cannot meet the standard of § 170.30 for a GRAS determination, as a food additive, and any dietary ingredient or dietary supplement that contains a food additive that we have not approved for use in the dietary ingredient or dietary supplement is subject to regulatory action. If the safety of such ingredient is not recognized expressly in an FDA regulation, you have the burden to explain why the ingredient is GRAS under § 170.30.

In the **Federal Register** of April 17, 1997, we issued a proposed rule on GRAS notification (62 FR 18938). We are currently accepting GRAS notifications under this proposed rule. However, we recognized in the GRAS notification proposal (62 FR 18938 at 18951) that a failure by us to object to a GRAS notification is not equivalent to a GRAS affirmation of GRAS status and we, as a matter of discretion, may not advise a notifier of a problem that we have identified that raises no important public health issues. Therefore, if you submit a GRAS notification to us under the April 17, 1997, proposed rule, our failure to object to your determination that an ingredient is GRAS in a dietary ingredient or dietary supplement will not constitute a GRAS affirmation by us. Further, if we know of no reason to question the safety and lawfulness of the ingredient that is the subject of a GRAS notification and that is used in the manufacture of a dietary ingredient or dietary supplement, we would not object to your reliance on your determination that the use of the substance is GRAS. You could not use our response to your GRAS notification as your basis for asserting compliance with the requirements under proposed § 111.35(d) because an FDA response letter to a GRAS notification is not the same as your explanation, *e.g.*, a response letter does not provide an explanation for why an ingredient is GRAS. We encourage any dietary ingredient or dietary supplement manufacturer to consult with us on any ''nondietary ingredient'' substance that it intends to use in such product to ascertain whether the use of such ingredient may be more appropriately submitted for review by us in a food additive petition.

Proposed § 111.35(e) would require that you establish a specification for any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration. These points, steps, or stages 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 prevent adulteration of the dietary ingredient or dietary supplement. These specifications are regulatory specifications and you would be required to perform testing or examination to confirm such regulatory specifications are met. We discuss performing testing or examination to confirm that a regulatory specification is met later in this document. A deviation from such specification would signify that the dietary ingredient or dietary supplement could be adulterated. Such deviation would require investigation and a disposition decision approved by the quality control unit under proposed § 111.35(i) (which we also discuss later in this document).

The proposed rule would not prevent you from establishing additional specifications that are not at points, steps, or stages where control is necessary to prevent adulteration if those additional specifications will help you meet your quality control demands, but a failure to meet those nonregulatory specifications will not require that you make a material review and disposition decision. In other words, you may establish additional specifications beyond those that the proposed rule would require, and a material review and disposition decision would be needed only for those specifications if not met, that are required under the proposed rule. For example, if you determine that a specific heat temperature is needed at a point, step, or stage in the manufacturing process to prevent adulteration, that heat temperature specification is a general regulatory specification. If not met, you would need to make a material review and disposition decision.

In addition, proposed § 111.35(e) identifies certain points, steps, or stages where a regulatory specification is required. Regulatory specifications are required for materials that you receive, at the inprocess stage, and that you manufacture, *e.g.*, at the finished product stage. Specifically, we are proposing to require that you establish specifications at these control points for the identity, purity, quality, strength,

and composition of the components (upon receipt only) and for dietary ingredients or dietary supplements (at all of these control points).

You may establish additional specifications (*i.e.*, those in addition to identity, purity, quality, strength, and composition) at these same control points. For example, you may determine that an inprocess specification is necessary during the manufacturing process to prevent adulteration. That inprocess specification would be a regulatory specification. Specifications also are needed for the inprocess materials to ensure that inprocess materials are not adulterated by the manufacturing process and are in compliance with the master manufacturing record. Additional specifications also may be needed for the finished product stage. Specifications are needed for dietary ingredients and dietary supplements you manufacture to ensure that the manufacturing process produces the correct dietary ingredient or dietary supplement and that adulterated and misbranded dietary supplements do not reach the marketplace.

Containers and closures are a form of packaging. The containers and closure or other packaging, such as blister pack, that comes in contact with dietary ingredients or dietary supplements must not be reactive or absorptive so as to affect the safety of the dietary ingredient or dietary supplement and must be composed of substances that are authorized by the agency for use as a food additive, the subject of a valid notification under section 409 of the act, authorized by a prior sanction issued by the agency, or GRAS for such use.

Thus, under this proposed requirement, you would be required to establish specifications for any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration. Specific specifications that would be required for you to establish include:

- The identity, purity, quality, strength, and composition of components, dietary ingredients, or dietary supplements that you receive;
- The inprocess controls in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;
- The identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement that you manufacture; and
- The packaging that may come in contact with dietary ingredients and dietary supplements. The packaging must be safe and suitable for its intended use and comply with all other applicable statutory and regulatory requirements under the act and must not be reactive or absorptive so as to affect the safety of the dietary ingredient and dietary supplement.

Proposed § 111.35(f) would require that, for each point, step, or stage, for which a specification is established under proposed § 111.35(e), you must monitor the production and inprocess control points, steps, or stages to ensure that they meet specifications and to detect any unanticipated occurrence that may result in adulteration. Regular monitoring of these points is necessary to ensure that the product meets the specifications under proposed § 111.35(e) and to ensure that any trend toward loss of control is quickly identified. Quick identification of any trends that may lead to a deviation from a specification could mean that adjustments may be made to prevent a deviation from occurring. In the event that a deviation or unexpected occurrence (such as leakage from a pipe onto a component) occurs, effective corrective actions can be taken to remove the adulterated product from the system.

Under proposed § 111.35(g) you must ensure through testing or examination that each specification that you establish under § 111.35(e) is met. Under § 111.35(e), you would have to determine the points, steps, or stages where control is necessary to prevent adulteration. However, there are certain points, steps, or stages in proposed § 111.35(e) that we tentatively have determined to be those where control is necessary to prevent adulteration. Specifically, we tentatively have determined that such control points include the receipt of components, dietary ingredients, or dietary supplements, the inprocess stage of manufacturing, and the finished product batch stage. Further, we tentatively have determined that at each of those control points, there need to be specifications for the identity, purity, quality, strength, and composition of components (only at receipt stage for components), dietary ingredients and dietary supplements (at all of these control points). In addition, we tentatively have determined that specifications are necessary for dietary ingredient and dietary supplement labels and packaging.

The testing and examination requirements in proposed § 111.35(g) would require that you conduct a test or examination to ensure that specifications that you established are met; *i.e.*, that you conduct a test or examination at those points, steps, or stages in the manufacturing process where you determined that a specification is needed to ensure that the specification, in fact, is met. For certain specifications that we would require, *i.e.*, the identity, purity, quality, strength, and composition upon receipt, inprocess, and at the finished product batch stage, we are providing some flexibility for testing. To illustrate, testing or examination requirements for specifications that you establish (*e.g.*, those other than the identity, purity, quality, strength, and composition of the dietary ingredients or dietary supplements received; inprocess, or finished product), such as for a botanical extraction process that uses a specific heat temperature for spray drying, you would be required to ensure by testing or examination that the specified temperature was used. You would be required to perform such a test or examination at the inprocess point, step, or stages where control is necessary. As another example, if a specific temperature is used on a finished batch of dietary ingredient or dietary supplement as a heat treatment to inactivate or remove objectionable microorganisms that pose a health hazard, and thus, the heat treatment temperature is a critical control point specification, then you must perform testing or examination to determine that the specific temperature was used. You would be required to perform such a test on each finished batch of dietary ingredient or dietary supplement that is manufactured.

For those specifications that we tentatively have determined are necessary (identity, purity, quality, strength, and composition) at receipt, inprocess, and finished product stage, we are proposing specific testing requirements that provide some flexibility. Under § 111.35(g)(1), we would require that you test each finished batch of the dietary ingredient or dietary supplement produced before releasing for distribution to confirm that specifications are met for the identity, purity, quality, strength, and composition intended, provided that there are scientifically valid analytical methods available to perform such testing. 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. Further, even though there may not be a scientifically valid analytical method that you could use to provide you with the information to evaluate, for example, the identity and composition of the finished

product, there may be methods available for testing at the finished product stage for other required specifications of purity, quality, and strength. Under proposed § 111.35(g)(3), your quality control must document that a scientifically valid analytical method is not available to perform finished product testing for any one of the required specifications for identity, purity, quality, strength or composition. If your quality control unit documents that a scientifically valid analytical method for testing each batch of dietary ingredient or dietary supplement is not available for any one of those required specifications, then you would be required, under § 111.35(g)(2)(i) and (g)(2)(ii) to test incoming shipment lots of components, dietary ingredients, or dietary supplements for any such specification to determine whether it is met and to test inprocess for any such specification in accordance with the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements.

Using a supplier certification, guarantee, or certification in lieu of performing testing on each shipment lot of components, dietary ingredients, or dietary supplements required in accordance with this section is not appropriate because it is possible that a supplier's certification or guarantee may not ensure the identity, purity, quality, strength, or composition of a component, dietary ingredient or dietary supplement. For example, a supplier of the dietary ingredient plantain provided a ''certificate of analysis'' indicating that the plant material was plantain powder, with a description of certain of its physical characteristics (Ref. 6). The plantain was contaminated with *D. lanata* (a plant that contains powerful heart stimulants that can cause life-threatening reactions including cardiac arrest, if ingested) and was distributed to at least 150 manufacturers, distributors, and retailers. Thus, if you do not perform finished product testing under § 111.35(g)(1) for identity, purity, quality, strength, or composition, then you would need to test for that nontested finished product specification upon receipt and inprocess as specified in the master manufacturing record to ensure that adulterated dietary ingredients or dietary supplements are not distributed to the marketplace.

If you are able to perform testing on each finished batch of dietary ingredient or dietary supplement to confirm that specifications are met for the identity, purity, quality, strength, and composition intended, then we would recommend, but would not require, that you also test materials received for these same specifications to ensure that they are the right ingredients and so that you do not end up having to destroy an entire batch of finished product after using an erroneous ingredient that could have otherwise been identified earlier before being added to a batch.

For example, if you manufacture a batch of dietary supplements that contains only one single dietary ingredient, St. John's Wort extract (*Hypericum perforatum*), and there are scientifically valid analytical methods available to test the finished dietary ingredient or supplement to confirm that the specifications are met for the identity, purity, quality, strength, and composition intended, then you must test each batch using such methods. In this example, you would not be required to perform testing of incoming shipment lots of St. John's Wort to confirm identity, purity, quality, strength, and composition to confirm that specifications are met nor would you be required to perform testing of inprocess for these same specifications in accordance with the master manufacturing record. As discussed later under proposed § 111.40(b)(2), although testing would not be needed at receipt stage for identity, purity, quality, strength, and composition, you would be required under that section, to visually compare the label, supplier's invoice, guarantee, or certification with your purchase order for consistency. In another example, if you manufacture a dietary supplement that contains multiple dietary ingredients (*e.g.*, Ginkgo Biloba, vitamin C, and folic acid) and you do not perform testing on the finished dietary supplement because there are not scientifically valid analytical methods available to confirm that the specifications for identity, purity, quality, strength, and composition are met for each dietary ingredient in the finished batch mixture, then you would be required to perform testing of incoming shipment lots of each dietary ingredient to confirm that such specifications are met and perform inprocess testing in accordance with the master manufacturing record to ensure that such specifications are met. Thus, the proposed testing requirements provide flexibility for testing for identity, purity, quality, strength, and composition, based on the availability of scientifically valid testing methods to perform testing on each batch of dietary ingredients or dietary supplements.

Proposed § 111.35(h) would require that you use an appropriate test or examination to determine whether your specifications are met. An appropriate test is one that is a scientifically valid analytical method. If there is an AOAC or FDA method available that is appropriate for your purpose, you should use that test method. For example, if your dietary supplement claims to contain vitamin C, there is a specific test for identifying vitamin C, and so proposed § 111.35(h) would require that you use that test (Ref. 68). 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. While there may not be an AOAC or FDA method available, we are not aware of a situation where an appropriate scientifically valid analytical method is not available. You could perform the tests yourself or have someone perform these tests for you.

Proposed § 111.35(i) would require that you must:

- Establish corrective action plans for use when an established specification is not met. We believe that this requirement is necessary because you may need to take corrective action quickly, and the best way to ensure that a corrective action is appropriate is to determine the action in advance. For example, if, during the production of a specific batch, the temperature specified for tablet coating drying is not met, you would be able to consult the corrective action plan to see whom you should contact, what correction to make, and when to make the correction. Having corrective action plans in place before a problem occurs can help you deal with those problems quickly and efficiently. As another example, if during production an operator notes that too low a temperature is used during a tablet coating drying operation, it would be best for the operator to have an action plan for immediate implementation, rather than having to stop the drying process to wait for instructions on what to do. Quick action may reduce the possibility of diminished changes in tablet dissolution or an adulterated product and enable you to avoid having to destroy incorrect tablets that are too moist or clump together or to avoid recalling a product because it settled into a clump or became moldy in the container;
- Review the results of the monitoring required by this section and conduct a material review of any component, dietary ingredient, dietary supplement, packaging or label for which you establish a specification that is not met, or any unanticipated occurrence that adulterates or could result in adulteration of the component,

dietary ingredient, dietary supplement, packaging, or label. This review will reveal whether the monitoring is actually being done and being done correctly, and whether the specifications are being met; and

• Make a material disposition decision for any component, dietary ingredient, dietary supplement, packaging, or label if:

1. A component, dietary ingredient, dietary supplement, packaging, or label fails to meet specifications;

2. Any step established in the master manufacturing record is not completed;

3. There is any unanticipated occurrence during the manufacturing operations that adulterates or may lead to adulteration of the component, dietary ingredient, dietary supplement, packaging, or label; or

4. Calibration of an instrument or control suggests a problem that may have caused batches of a dietary ingredient or dietary supplement to become adulterated; and

5. A dietary ingredient or dietary supplement is returned.

• Have your quality control unit approve any material review and disposition decision.

You should review the public health significance of any deviations from specifications or of any unexpected occurrences to ensure that dietary ingredients and dietary supplements that may have been affected adversely by a deviation do not enter the marketplace. A material review and disposition decision would ensure that the disruption of a manufacturer's business is minimized when a deviation does occur. For example, if review of a dietary supplement formulation does not contain the required identity, purity, quality, strength, or composition, you can take steps to dispose of the formulation before it is packaged and labeled. If the monitoring records are not reviewed, a dietary supplement made with a deficient formulation may be placed on the market, and a costly and embarrassing recall may be necessary.

Proposed § 111.35(i)(4) 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, the proposal would require that you reject the component, dietary ingredient, dietary supplement, packaging, or label, unless the quality control unit determines that inprocess adjustments are possible to correct the deviation or occurrence. You would be able to reprocess a rejected component, dietary ingredient, or dietary supplement if the quality control unit approves such reprocessing. However, the proposal states that you must not reprocess any component, dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms or other contaminants, such as heavy metals. We propose to prohibit reprocessing in such cases because it is unlikely that reprocessing will eliminate such forms of contamination or will eliminate such contamination without adversely affecting the component, dietary ingredient, or dietary supplement.

Proposed § 111.35(i)(5) would require that this review be conducted by an individual from the quality control unit. This is necessary to ensure that the review is conducted by a person who is qualified by training and experience to conduct such reviews and who understands the production and inprocess control system, understands the significance of a processing deviation, and knows how to respond to a deviation. This will ensure that the review that is conducted and the response to any deviation is appropriate. The requirements of this section do not mean that the manufacturer needs a large number of employees.

Proposed § 111.35(j) would require the person who conducts the material review and makes the disposition decision to document, at the time of performance, every material review and disposition decision in proposed § 111.35(i). The documentation must be included in the batch production record. Proposed § 111.35(j) would require this documentation to:

• Identify the specific deviation from the specification or the unanticipated occurrence;

• Describe your investigation into the cause of the deviation from the specification or the unanticipated occurrence;

• Evaluate whether or not the deviation from the specification or unanticipated occurrence has resulted in or could lead to adulteration;

• Identify the action(s) taken to correct and prevent a recurrence of the deviation or the unanticipated occurrence; and

• Discuss what you did with the component, dietary ingredient, dietary supplement, packaging, or label. For example, did you segregate the component? Did you quarantine it until the quality control unit decided whether it should be returned to its supplier, reprocessed, or destroyed?

Proposed § 111.35(k) would require that you test or examine components, dietary ingredients, and dietary supplements for those types of contamination that may adulterate or may lead to adulteration.

The proposal also would require that you use an appropriate scientifically valid methodology for the test or examination. We discuss analytical methods in more detail elsewhere in this document in our discussion of laboratory operations, proposed § 111.60. The types of contamination covered by proposed § 111.35(k) include, but are not limited to, the following:

• Filth, insects, or other extraneous material;

• Microorganisms; and

• Toxic substances.

Under this proposed requirement, you must test or examine for those types of contamination that may adulterate or may lead to adulteration. The words, ''for those types of contamination that may adulterate or may lead to adulteration,'' at least in part, mean that you must test a botanical for filth and microorganisms of public health significance. For example, it is highly likely or certain that botanical components would be contaminated with filth and undesirable microorganisms of public health significance based on the areas in which they are harvested. Therefore, it would be inappropriate if you did not test botanical components for filth and microorganisms. The types of tests and when to test would be left to your discretion. The proposed rule would not specify any particular test or examination, so you would be able to decide on the appropriate methods for testing or examination that are suited to your components, dietary ingredients, and dietary supplements.

Contamination also can create conditions that promote further contamination by other organisms. For example, contamination resulting from possible fungal growth on a botanical component can provide the environment for mycotoxin production, especially aflatoxin (Refs. 63 and 64). Therefore, if a toxic substance is a type of contamination that may adulterate or lead to adulteration of the dietary ingredient or dietary supplement, you must perform an appropriate test to detect the toxic substance.

In other cases, a certain amount of micro flora on a botanical may be unavoidable. For example, some botanical components always will contain a certain number of microorganisms that live on the plant or come from other organisms (micro flora) on the plant. Processing these components may destroy a substantial number of the microorganisms, but some may survive processing (Ref. 65).

Therefore, for natural products it may be appropriate to perform tests of finished product to confirm that, of the microorganisms present, those of public health significance did not survive processing and those that remain that are not of public health significance do not contaminate the dietary ingredient or dietary supplement.

Although the proposal does not specify microbial limits for undesirable microorganisms, other non-FDA sources have established acceptable, general limits of microbial levels for dietary ingredients and dietary supplements (Refs. 66 and 67). These often include limits for total aerobic microbial count, which ranges from $10^4$ to $10^7$ per g, depending on source and nature of components; a total combined yeast and molds count, which can range from $10^3$ to $10^5$ per g, again depending on source and nature of components; and the absence of *Salmonella* species, *E. coli* and *Staphylococcus aureus.* We establish microbial limits for undesirable microorganisms based on scientific information such as literature surveys and laboratory analyses. At this time, however, we do not have sufficient information to support establishing microbial limits for undesirable microorganisms for dietary ingredients. Therefore, the proposed rule does not establish microbial limits for dietary ingredients. However, you must be aware of potential contamination, regardless of whether it is due to filth, insects, microorganisms, or toxins, and you must test or examine as appropriate components, dietary ingredients, or dietary supplements for those types of contamination that may adulterate or may lead to adulteration.

Proposed § 111.35(l) would explain that the tests you use to determine whether your components, dietary ingredients, and dietary supplements meet specifications must include at least one of the following tests: Gross organoleptic analysis, microscopic analysis, chemical analysis, or other appropriate test. These tests may vary in detail or complexity depending on the purposes of the test and the material being tested. For example, if your component is raw cranberries, and you are trying to verify that a shipment of red berries consists of raw cranberries, an organoleptic (visual test) may be sufficient (assuming that you recognize cranberries). However, if your component is a chemical substance, and you are trying to verify that a shipment of bulk powder is that chemical substance, chemical analysis may be more appropriate than an organoleptic analysis.

Proposed § 111.35(m) would require that you must record the results of all testing and examinations performed in accordance with this section. If a test or examination is performed on a production batch, you must record the test or examination result in the batch production record in accordance with § 111.50(c)(10). Your records must document whether the testing and examination demonstrates that specifications are met.

Proposed § 111.35(n) would require for any specification that is not met, that you must conduct a material review and disposition decision under § 111.35(i).

Proposed § 111.35(o) would require that you make and retain records, in accordance with proposed § 111.125, to ensure that you follow the requirements of this section. The proposal would require these records to include, but would not limit them to:

- The specifications established;
- The actual results obtained during the monitoring operation;
- Any deviation from specifications and any unanticipated occurrences;
- Any corrective actions taken;
- The disposition decisions and followup; and
- The identity of the individual qualified by training and experience who investigated any deviation from specifications or unanticipated occurrence and the identity of the individual from the quality control unit who reviewed the results of that investigation.

These records would enable you to show, and for us to determine, your compliance with proposed § 111.35. We generally determine CGMP compliance by conducting inspections, so records play an important role during those inspections in determining CGMP compliance.

2. What Requirements Apply to Quality Control? (Proposed § 111.37)

Proposed § 111.37(a) would require that you use a quality control unit to ensure that your manufacturing, packaging, label, and holding operations in the production of dietary ingredients and dietary supplements are performed in a manner that prevents adulteration and misbranding, including ensuring that dietary ingredients and dietary supplements meet specifications for identity, purity, quality, strength, and composition. This requirement does not mean that the manufacturer needs a large number of employees. The manufacturing process for an ingredient or a dietary supplement can be a sophisticated process, and all organizational units that are involved in critical formulation and manufacturing steps, such as production, engineering, research, and regulatory affairs, may be included in quality control functions.

Proposed § 111.37(b) would require that your quality control unit must do the following:

- Approve or reject all process, procedures, specifications, controls, tests, and examinations, and deviations from or modifications to them that may affect the identity, purity, quality, strength, and composition of a dietary ingredient or dietary supplement;
- Determine whether all components, dietary ingredients, dietary supplements, packaging, and labels conform to their specifications;
- Approve or reject all components, dietary ingredients, dietary supplements, packaging, and labels;
- Review and approve all master manufacturing records and all modifications to the master manufacturing records;
- Review and approve all batch production-related records which include, but are not limited to, cross-referencing receiving and batch production records, approval of a material review and disposition decision, approval for reprocessing, and approval for releasing for distribution. Cross-referencing receiving and batch production records means that the quality control unit must verify that the batch record includes certain documentation of the receiving records for the components and dietary ingredients 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.
- Review and approve all processes for calibrating instruments or controls;
- Review all records for calibration of instruments, apparatus, gauges, and recording devices;
- Review all records for equipment calibrations, inspections, and checks;
- Review and approve all laboratory control processes and testing results;
- Review and approve all packaging and label records which include, but are not limited to, cross-referencing receiving and batch production records, approval for repackaging and relabeling, and approval for releasing for distribution;
- Collect representative samples of:

1. Each shipment lot of components, dietary ingredients, dietary supplements, packaging, and labels received for testing or examination, as needed, to determine whether the component, dietary ingredient, dietary supplement, packaging, or labels meet specifications before use or for testing,

as needed, in consumer complaint investigations;

2. Inprocess materials 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, quality, strength, and composition of dietary ingredients or dietary supplements;

3. Each batch of dietary ingredient or dietary supplement that is manufactured to determine, before you release it for distribution, whether it meets its specifications for identity, purity, quality, strength, and composition; and

4. Each batch of packaged and labeled dietary ingredients or 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;

• Review and approve all material review and dispostion decisions; and

• Collect representative reserve samples of each shipment lot of components, dietary ingredients, and dietary supplements and each batch of dietary ingredient or dietary supplement. The proposal would require that you keep the reserve samples for 3 years from the date of manufacture for use in appropriate investigations, such as, consumer complaint investigations to determine, for example, whether the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition. We tentatively decide to require that you keep reserve samples for 3 years because we believe that 3 years would be a reasonable time period beyond the date of manufacture for appropriate followup of consumer complaints received during the marketing period. Because we have not proposed requirements for expiration dating of dietary supplements, we tentatively conclude that the date of manufacture is an appropriate starting time for the retention period. This requirement in proposed § 111.37(b)(11) also would require that the reserve samples be identified with the batch or lot number and consist of at least twice the quantity necessary for tests;

• Perform appropriate tests and/or examinations of:

1. Components, dietary ingredients, dietary supplements, packaging, and labels received to ensure that they meet specifications;

2. Dietary ingredient and dietary supplement batch production at points, steps, or stages identified in the master manufacturing record where control is necessary to prevent adulteration;

3. Dietary ingredients and dietary supplements that you manufacture to ensure that they meet specifications; and

4. Packaged and labeled dietary ingredients and dietary supplements to ensure that you used the packaging specified in the master manufacturing record and you applied the label specified in the master manufacturing record;

• Review and approve all material review and disposition decisions; and

• Approve the reprocessing or distribution of returned dietary ingredients or dietary supplements.

Proposed § 111.37 would impose duties on your quality control unit that are necessary to the quality control unit. The duties proposed in § 111.37 are important in any CGMP standards to ensure that the dietary ingredient or dietary supplement manufactured has the identity, purity, quality, strength, and composition intended. If a quality control unit did not do, that is, lacked the responsibility and authority to do, the actions described in proposed § 111.37, coordination between various parts of your manufacturing, packaging, or holding operation might become haphazard and the product could be adulterated. For example, if your quality control unit did not make decisions concerning use of components, dietary ingredients, and dietary supplements you receive, you could use the wrong component, or a contaminated component in manufacturing a dietary ingredient or dietary supplement. If your quality control unit makes decisions concerning releasing dietary ingredients and dietary supplements for distribution, it will prevent you from releasing for distribution an adulterated dietary ingredient or dietary supplement before the necessary tests results confirm that the dietary ingredient or dietary supplement meets specifications for identity, purity, quality, strength, and composition.

Your quality control unit must document, at the time of performance, that it performed the review, approval, or rejection requirements established in accordance with proposed § 111.37 by recording the date when the review, approval, or rejection and requirement was performed, and the signature of the person performing the requirement. As we explained elsewhere in this document, one of the ways we determine compliance with CGMP's is by conducting inspections, so records enable you to show, and for us to determine, compliance with CGMP's. We invite comment on whether we should require, in a final rule, written procedures for the quality control unit duties required in § 111.37. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

3. What Requirements Apply to Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels You Receive? (Proposed § 111.40)

Proposed § 111.40 would establish requirements to ensure that the components, dietary ingredients, dietary supplement, packaging, and labels you receive are, in fact, what you ordered. We are proposing these requirements because receiving the wrong materials can lead to mixups or the use of wrong materials and this could result in the manufacture of an adulterated and misbranded dietary ingredient or dietary supplement.

Proposed § 111.40(a)(1) and (a)(2) would apply to components, dietary ingredients, or dietary supplements you receive, and would require that you:

• 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's condition has resulted in contamination or deterioration of the components, dietary ingredients, or dietary supplements;

• Visually examine the supplier's invoice, guarantee, or certification to ensure that the components, dietary ingredients, or dietary supplements are consistent with your purchase order and perform testing, as needed, under proposed § 111.35(g), to determine whether specifications are met.

We state in proposed § 111.40(a)(2) that you must perform testing ''as needed.'' This flexibility is necessary, given the proposed testing scheme in § 111.35(g). As previously discussed in proposed § 111.35(e), you must establish specifications for any points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration. In addition, we propose to require, under § 111.35(e), certain

specifications, *i.e.*, identity, purity, quality, strength, and composition, for components, dietary ingredients, and dietary supplements upon receipt. However, in § 111.35(g), we are proposing to provide some flexibility for when testing is required for the identity, purity, quality, strength, and composition specifications. Specifically, if you perform finished product testing under § 111.35(g)(1) for identity, purity, quality, strength, and composition, then under § 111.40(a)(2) we would require that you visually compare the supplier's invoice, guarantee, or certification with your purchase order to confirm consistency between your order and the supplier's invoice, guarantee, or certification. You would not need to do testing upon receipt. That is why we have added language to § 111.40(a)(2) that states, ''and perform testing, as needed, to determine whether specifications are met.'' Alternatively, for specifications that you establish (*e.g.*, other than the identity, purity, quality, strength, and composition of the components, dietary ingredients or dietary supplements received), such as for a holding temperature necessary during transportation to your physical plant to avoid adulteration, you would be required to ensure by testing or examination that the specified temperature was used.

If you do not perform finished product testing under § 111.35(g)(1) for identity, purity, quality, strength, or composition, then you would need to test for that nontested finished product specification upon receipt. In that case, testing would be needed under both proposed §§ 111.35(g)(2) and 111.40(a)(2). You still would need to visually compare the supplier's invoice, guarantee, or certification with your purchase order to confirm consistency between your order and the supplier's invoice, guarantee, or certification.

Thus, for those specifications of identity, purity, quality, strength, or composition for which your quality control unit determines that you cannot test for at the finished product stage (because there are no available scientifically valid methods), then you would be required, under § 111.35(g)(2)(i) to test incoming shipment lots of components, dietary ingredients, or dietary supplements for any such specification to determine whether it is met, and such a test also would be considered to be necessary under § 111.40(a)(2). As discussed earlier, you may not rely on a supplier's certification or guaranty in lieu of such testing, and in addition to such testing, still would need to visually examine the supplier's invoice, guarantee, or certification.

Under § 111.40(b)(3) through (b)(5), we would require that you:

- Quarantine components, dietary ingredients, or dietary supplements until your quality control unit reviews the supplier's invoice, guarantee, or certification and performs testing, as needed under proposed § 111.35(g), of a representative sample to determine that specifications are met. These are the specifications that you would set in accordance with proposed § 111.35(e) and appropriate tests or examinations used in accordance with proposed § 111.35(g) for materials that you receive. If specifications are not met, proposed § 111.40(a)(3) would require that you conduct a material review and make a disposition decision. Your quality control unit must approve and release the components, dietary ingredients, and dietary supplements from quarantine before you use them;
- Identify each lot of components, dietary ingredients, or 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 component or dietary supplement, and the status (*e.g.*, quarantined, approved, or rejected) and to trace the shipment lot to the dietary ingredient or dietary supplement manufactured and distributed. You must use this unique identifier whenever you record the disposition of each shipment lot received. Using a unique identifier throughout the manufacturing process will make it possible to track and account for components, dietary ingredients, and dietary supplements you receive and is necessary to conduct investigations of consumer complaints; and
- Hold components, dietary ingredients, or dietary supplements under conditions that will protect against contamination, deterioration, and avoid mixups. For example, you must segregate components that your quality control unit has not released for use from those components that have been released for use. This provision would require that you refrigerate components that are subject to contamination or deterioration without such refrigeration or that otherwise require storage at a certain temperature.

Proposed § 111.40(b) would apply to packaging and labels you receive and would require that you:

- Visually examine each container or grouping of containers in a shipment for appropriate content labels, container damage, or broken seals to determine whether the container's condition has resulted in contamination or deterioration of the packaging and labels;
- Quarantine packaging and labels until your quality control unit tests or examines a representative sample to determine that specifications are met. You must conduct at least a visual identification on the containers and closures. If specifications are not met, the proposal would require that you conduct a material review and make a disposition decision and also require your quality control unit to approve and release packaging and labels from quarantine before you use them;
- 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 ingredient or dietary supplement manufactured and distributed. Like proposed § 111.40(a)(4), proposed § 111.40(b)(3) would require that you use this unique identifier whenever you record the disposition of each shipment lot received; and
- Hold packaging and labels under conditions that will protect against contamination and deterioration and avoid mixups.

Proposed § 111.40(c) deals with written documentation and records. Proposed § 111.40(c)(1) would require that the person who performs the requirements established in accordance with this section to document, at the time of performance, that he or she performed the requirements. The documentation would have to include, but not be limited to, the date that the requirement was performed; the signature of the person performing the requirement; any test results; and any material review and disposition decision conducted, and the disposition of any rejected material.

Proposed § 111.40(c)(2) would require that you keep component, dietary supplement, packaging, and label receiving records in accordance with proposed § 111.125. These records are necessary to be able to determine the source of the component, dietary ingredient, dietary supplement, packaging, and labels, so that if adulteration of dietary ingredient or dietary supplement occurs, the records will show the source of the material so that its use can be stopped. In addition, the records will show the basis on which each component, dietary ingredient, dietary supplement, packaging, or label was released for use in dietary ingredient or dietary supplement production. These records

are necessary to demonstrate compliance with the CGMP and quality control procedures.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures that implement proposed § 111.40(a) and (b). 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

4. What Requirements Apply to Establishing a Master Manufacturing Record? (Proposed § 111.45)

Proposed § 111.45 would require that you prepare and follow a written master manufacturing record for each type of dietary ingredient or dietary supplement that you manufacture and for each batch size to ensure uniformity from batch to batch. 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 amount the recipe calls for, *e.g.*, 250 mg, 500 mg, vitamin C. 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 would not add all of the necessary components in the appropriate strength or amount, and this would result in an adulterated ingredient or dietary supplement.

Therefore, proposed § 111.45(a) is necessary to ensure that you prepare and follow a written master manufacturing record for each type of dietary ingredient or dietary supplement to ensure that all the necessary components as specified, and in the amounts specified, are used to manufacture each batch to ensure uniformity from batch to batch and to ensure that the dietary ingredient or dietary supplement is not adulterated. Proposed § 111.45(a)(1) and (a)(2) describe the proposed contents of the master manufacturing record. The master manufacturing record would identify specifications for the points, steps, or stages in the master manufacturing record where control is necessary to prevent adulteration, and establish controls and procedures to ensure that each batch of dietary ingredient or dietary supplement manufactured meets those specifications. For example, assume that your manufacturing process blends various ingredients in order to make a dietary supplement. Under proposed § 111.45(a), your master manufacturing record would establish controls to look at specific steps in the manufacturing process and evaluate the blends for specific ingredients to ensure that you added the correct ingredients at the correct amounts or concentrations that meet your specifications before the blend proceeds to the next manufacturing step, in accordance with the master production record. Throughout the manufacturing process, you would evaluate, as necessary, any points, steps, or stages where control is necessary to prevent adulteration to ensure that specifications established for those points, steps, or stages are met.

Proposed § 111.45(b) would establish additional requirements for the master manufacturing record. These proposed requirements would include:

- The name of the dietary ingredient or dietary supplement to be manufactured and the strength, concentration, weight, or measure of each dietary ingredient for each batch size. For example, assume you have a million tablet batch size of a vitamin C product in 250 mg tablets and that the only other ingredients in your product are starch, microcrystalline cellulose, and dicalcium phosphate. Under proposed § 111.45(b)(1), your master manufacturing record would state, ''Vitamin C 250 mg, 1,000,000 tablets'';
- A complete list of components to be used. Again, to continue using the example immediately above, for proposed § 111.45(b)(2), the master manufacturing record also would show that you used starch, microcrystalline cellulose, and dicalcium phosphate in the product;
- An accurate statement of the weight or measure of each component to be used. For example, under proposed § 111.45(b)(3), the master manufacturing record for our hypothetical vitamin C tablet would state the amount of each component used, such as ''200 lbs. of Vitamin C, 10 lbs. of microcrystalline cellulose'' and the amounts of starch and dicalcium phosphate used. (We would not require that you show the amount using an appropriate English or metric standard in a particular way, but we would expect that you use the most appropriate weight or measure for the component);
- 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 in compliance with section 403(s) of the act. For proposed § 111.45(b)(4), therefore, the master manufacturing record for our hypothetical product would state that the dietary ingredient is Vitamin C at 250 mg (because Vitamin C would be the dietary ingredient declared on the Supplement Facts label) and identify starch, microcrystalline cellulose, and dicalcium phosphate (because those ingredients would be in the product's ingredient list, but not on the Supplement Facts label); and
- A statement that explains any intentional excess amount of a dietary ingredient. We recognize that some manufacturers intentionally add a specific amount of a dietary ingredient in excess of the declared label amount so that the finished product can meet the label declaration for that dietary ingredient throughout the product's shelf life. For our hypothetical vitamin C tablet, if you added an extra 25 mg of vitamin C to ensure that your product contains at least 250 mg of vitamin C throughout its shelf life, your master manufacturing record would state the component and the actual amount of the component as ''Vitamin C, 250 mg, (10 percent excess) 25 mg'' or ''275 mg of Vitamin C.'' So, proposed § 111.45(b)(5) would require the master manufacturing record to specify the controlled amount of the excess dietary ingredient necessary to achieve the declared label declaration. This provision is not intended to allow a manufacturer to add excess dietary ingredients in unspecified amounts that would be in excess of the amount actually needed to meet the label declaration.

The agency considered whether to propose requirements in this proposed rule for expiration dating, shelf-life dating, or best if used by dating (hereinafter referred to as expiration dating). Although we recognize that there are current and generally available methods to determine the expiration date of some dietary ingredients, for example vitamin C, we are uncertain whether there are current and generally available methods to determine the expiration dating of other dietary ingredients, especially botanical dietary ingredients. We are not proposing expiration dating at this time because we have 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 (*i.e.*, AOAC or FDA) for dietary supplements are evolving, especially for botanical dietary ingredients, few official methods are available to assess the strength of a dietary ingredient in a dietary supplement. Nevertheless, if you use an expiration date on a product, you should have data to support that date. You should have a written testing program designed to assess the stability characteristics of the dietary supplement, and you should use the results of the stability testing to determine appropriate storage conditions and expiration dates.

We invite comment on whether any final dietary ingredient and dietary supplement CGMP rule should contain provisions regarding expiration dating and the feasibility of conducting tests needed to support such dates. We also invite comments 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.

Proposed § 111.45(b) also would require your master manufacturing record to contain:

- A statement of theoretical yield of a manufactured dietary ingredient or dietary supplement expected at each point, step, or stage of the manufacturing process where control is necessary to prevent adulteration, and the expected yield when you finish manufacturing the dietary ingredient or dietary supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is performed and material review is conducted and disposition decision is made. In this particular instance, when we refer to the manufacture of dietary ingredients, we mean to say that if you use a master manufacturing record to make dietary ingredients (that is, you make dietary ingredients rather than dietary supplements), the proposal would require the master manufacturing record to contain a theoretical yield at each point, step, or stage where control is necessary to prevent adulteration. Likewise, if you manufacture dietary supplements, the proposal would require your master manufacturing record to contain a theoretical yield at each point, step, or stage where control is necessary to prevent adulteration;
- A description of packaging and a copy of the label to be used. We propose to require such information because, depending on the type of material you use, packaging could adulterate your dietary ingredients or dietary supplements. For example, the correct container may protect the dietary ingredient or dietary supplement from the deteriorating effects of light and if an incorrect container is used that does not provide this protection, your dietary ingredient or dietary supplement could deteriorate and could be adulterated. The description might consist of information such as the type of bottle to be used with your manufacturer's code number, if available; a description of the cap to be used with the liner specified with a manufacturer's code number, if applicable; additional materials needed in packaging; and the control number, if applicable, of the label to be used in packaging the dietary ingredient or dietary supplement. We are not aware of evidence of that dietary supplement manufacturers are using unlawful containers. Section 201(s) of the act defines ''food additive'' to mean any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in it's becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use). Materials used in packaging that come in contact with food or that react chemically with food, may be considered to be food contact substances or food additives. Foods and dietary ingredients may contain active substances that can react with packaging materials. Thus, FDA is proposing a CGMP requirement that manufacturer's use containers that are lawful under the act and that do not impose a risk such as leakage or the possibility of physical contamination of dietary ingredients or dietary supplements. Information on packaging and labels materials will also be helpful in case an adverse event occurs; and
- Written instructions including, but not limited to:

1. Specifications for each point, step, or stage in manufacturing the dietary ingredient or dietary supplement necessary to prevent adulteration;
2. Sampling and testing procedures;
3. Specific actions necessary to perform and verify points, steps, or stages, necessary to meet specifications and otherwise prevent adulteration, including, but not limited to, one person weighing or measuring a component and another person verifying the weight or measure and 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.

You should think of the written instructions as being similar to a recipe; they should cover the important steps in your manufacturing, packaging, or holding processes, but they also should tell the reader about any special directions to follow, tests to perform, precautions to be observed, and personnel to use.

Proposed § 111.45(c) would require that you have your quality control unit review and approve each master manufacturing record and any modifications to a master manufacturing record. This provision reiterates the quality control requirements in proposed § 111.37. This proposed requirement is necessary to prevent potential problems that could result from changes to the master manufacturing record made by persons who are not qualified to assess the impact of such changes. By having your quality control unit review and approve the master manufacturing record and changes to that record, you will reduce your risk of not detecting the inclusion of an incorrect ingredient in the batch production. The quality control unit review will ensure that necessary inprocess verifications and testing instructions are included in the master manufacturing record. Further, any changes to the master manufacturing record will reduce your risk of adding the wrong component, dietary ingredient or dietary supplement or the wrong amount of a component, dietary ingredient or dietary supplement. For example, in one case, a dietary supplement manufacturer made a product that had 10 times the labeled amount of vitamin D, but did not perform any tests for vitamin D concentration as part of its review of its batch records (Ref. 23). The manufacturer discovered the superpotent batches only after State authorities had contacted them, and had to recall the product. Had the manufacturer's quality control unit reviewed the master manufacturing and batch production records earlier, the superpotent batches that represented a change from the master manufacturing record might have been detected before the product left the manufacturer, and the recall could have been avoided. The manufacturer later took steps to increase its audits of batch records, to require approval of all changes to its master

formulas, and to perform tests for its manufacturing activities.

In another example, several consumers and employees at spas in Massachusetts and Arizona complained of dizziness, vomiting, or lightheadedness after consuming several dietary supplements. We did an inspection and found that, in the case of two products, the manufacturer's formula called for the use of a product having 0.2 percent selenium by weight, but the manufacturer's records showed that it used a product that had 5 percent selenium by weight. This difference meant that the supplements, instead of containing 200 µg of selenium, contained between 400 to 4,699 µg of selenium. After further investigation, we determined that the error occurred when the quantity of selenium to be used was printed in kilograms (kg), instead of g. The change in unit measurement represents a change from the master manufacturing record. Had the manufacturer's quality control unit reviewed the change in the master manufacturing record, it probably would not have approved the change to include use of the product containing the higher percent of selenium.

One comment to the ANPRM opposed a requirement that would have a quality control unit review and approve the master manufacturing record. The comment stated that this review and approval process is overly restrictive because other units can perform this function and only need be audited or periodically verified by the quality control unit. The comment suggested that the quality control unit assure that a master production and control record must be prepared for the manufacture of each dietary ingredient and dietary supplement, rather than review and approve such records.

We do not agree that the review and approval process is overly restrictive and decline to adopt the comment's suggestion. The quality control unit can be composed of individuals from various parts of the organization. Removing this responsibility from the quality control unit would diminish the quality control unit's responsibility and authority. As stated earlier, the manufacturing process of a dietary ingredient or a dietary supplement can be a sophisticated process, and we understand that all organizational units that are involved in critical formulation and manufacturing steps, such as production, engineering, research, and regulatory affairs, should review and approve a master production order and changes to it. However, the responsibility for reviewing and approving the master manufacturing record and modifications to that record properly rests with the quality control unit because the individuals in the quality control unit would have the expertise to make a decision whether the master manufacturing record, if followed, will result in an unadulterated dietary ingredient or dietary supplement and does not mean that the manufacturer needs a large number of employees.

You should note that, while the quality control unit is responsible for reviewing and approving the master manufacturing record and changes to that record, this does not mean that the quality control unit must prepare the master manufacturing record itself or act without any involvement from other parts of your manufacturing operation. Other individuals or groups may help prepare, review, and approve drafts of a master manufacturing record and draft changes to an existing master manufacturing record, but the quality control unit is responsible for reviewing and approving the final master manufacturing record and modifications to that record.

Proposed § 111.45(d) would pertain to written documentation and recordkeeping. Proposed § 111.45(d) would require that you keep your master manufacturing records in accordance with proposed § 111.125. The master manufacturing record in addition to the batch production records will ensure that a complete history of each batch of dietary ingredient or dietary supplement is available for your review in the event that a problem arises with a particular batch. These records also are necessary to demonstrate compliance with the CGMP and quality control procedures.

We invite comment on whether a written procedure for preparing the master manufacturing record and making any modifications to the record, consistent with the requirements in this section, should be required in a final rule. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

5. What Requirements Apply to Establishing a Batch Production Record? (Proposed § 111.50)

Proposed § 111.50(a) would require that you prepare a batch production record every time you manufacture a batch of dietary ingredient or dietary supplement. This requirement would apply to any batch, including a batch approved for reprocessing by the quality control unit. The proposal also would require the batch production record to include complete information relating to the production and control of each batch. The batch production record is necessary to document that you followed the master manufacturing record to make each batch of dietary ingredients or dietary supplements. It is important to document such information for each batch because it serves as a check that the master manufacturing record was followed. If you later discover problems with a particular batch of dietary ingredients or dietary supplements, you could look at the batch production record for that batch, compare it to the master manufacturing record, and see whether the problems occurred because of a failure to follow the master manufacturing record. These records, in conjunction with your master manufacturing records, will create a written system which, when followed, will result in a reproducible, high-quality, and uniform dietary ingredient or dietary supplement.

Proposed § 111.50(b) would require the batch production record to accurately follow the appropriate master manufacturing record and also require that you perform each step in producing the batch. Even if you have someone else (such as a contractor) perform a particular step, you would remain responsible for ensuring that each step is done that complies with the

requirements in proposed part 111. The contractor, however, is also considered a manufacturer and must comply with the regulations that apply to the responsibilities that it has specifically contracted to perform.

Proposed § 111.50(c) would specify the batch production record's contents. The proposal would require that certain information be included in the batch production record including, but not be limited to, the following information:

- The batch, lot, or control number;
- Documentation, at the time of performance, showing the date on which each step of the master manufacturing record was performed, and the initials of the persons performing each step including, but not limited to, the person responsible for weighing or measuring each component used in the batch and the person responsible for adding the components to the batch;
- The identity of equipment and processing lines used in producing the batch;
- The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch;
- The shipment lot unique identifier of each component, dietary ingredient, dietary supplement, packaging, and label used;
- The identity and weight or measure of each component used;
- The initials at the time of performance or at the completion of the batch of the person responsible for verifying the weight or measure of each component used in the batch;
- The initials at the time of performance or at the completion of the batch of the person responsible for verifying the addition of components to the batch;
- A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;
- The actual test results for any testing performed during the batch production in accordance with § 111.35(m);
- Documentation that the dietary ingredient and dietary supplement meets specifications;
- 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;
- Any documented material review and disposition decision in accordance with § 111.35(j); and
- The signature of the quality control unit to document batch production record review and any approval for reprocessing or repackaging.

Proposed § 111.50(b) and (c) are necessary to ensure that you made your batches correctly under the master manufacturing record and that you correctly performed each significant step in the manufacturing process. If you did not create a batch production record for each batch production that accurately followed the master manufacturing record, you would not be sure that your dietary ingredient or dietary supplement was not adulterated. The master manufacturing record is intended to ensure batch to batch uniformity and to prevent adulteration. Your batch production record also may be valuable in the event of a product recall. We seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

In one case (Ref. 27), we found that a manufacturer had produced a subpotent folic acid product. When the manufacturer reviewed the batch production records, it discovered that the bulk product was not mixed properly, and this caused the folic acid to be distributed poorly throughout the product. Thus, in this instance, the batch production record helped identify the point in the manufacturing process when the error occurred, and the reason why the error occurred and enabled the manufacturer to correct the problem.

Review of batch production records might have prevented another incident where several persons experienced dizziness, vomiting, or lightheadedness after consuming vitamin and mineral products. As we mentioned in our discussion of proposed § 111.45, this incident involved a mixup during the manufacturing process where the manufacturer's master manufacturing record called for the use of a product having 0.2 percent selenium by weight, but the manufacturer's batch records showed that it used a product that had 5 percent selenium by weight. This difference meant that the supplements, instead of containing 200 μg of selenium, contained between 400 to 4,699 μg of selenium. As discussed earlier, the quality control unit review and approval of the master manufacturing record would have noted the change in percent selenium by weight and the necessary changes to the master manufacturing record could have been made. The quality control unit review and approval of the batch production record provides another check to ensure that a mixup has not occurred. Had the manufacturer's quality control unit compared the master manufacturing record to the batch production record, it would have noticed the mixup during the manufacturing process and prevented the use of the higher percentage selenium dietary ingredient. The information that would be required under proposed § 111.50(c) would help you determine what product was manufactured, when it was manufactured, how it was manufactured, and where it was manufactured. As another example, if your batch production records identify the equipment and processing lines being used, you would be able to go to that piece of equipment or to that processing line and determine which dietary ingredient or dietary supplement is being manufactured or processed. Further, if your batch records reflect the initials of those persons who weighed a component, added that specific component, and performed a particular step to prevent adulteration of the product, you would be able to see who was responsible for a particular action and, if necessary, to consult that person in the event of a problem or to see how he or she performed a particular task. In addition, if your batch production records contain batch or lot numbers and if you later discover a problem with a particular batch, that information will help you investigate the problem by showing you the manufacturing history for that particular batch.

A comment to the ANPRM stated that keeping written records of equipment cleaning and use, including the date, product, and lot number of each batch processed, would be burdensome compared to the benefits it would provide, particularly when equipment is cleaned after each use. The comment added that manufacturers can modify their production records to note which machines they used.

We disagree with the comment. Written records will help you to ensure that all cleaning operations are performed correctly and, if problems do occur with the production of a product, will help you determine whether those

problems are associated with maintenance, cleaning, or sanitizing operations. Batch and lot information, as we stated earlier, will let you identify batches or lots that may have been affected by any equipment or utensil that was improperly maintained, cleaned, or sanitized.

Proposed § 111.50(d) and (e) would set forth your quality control unit's responsibilities regarding batch production records. These responsibilities relate to not only the review but the documentation of their review and decisions about whether a batch could be reprocessed. As we noted in our discussion of proposed § 111.37, the quality control unit has special knowledge and expertise to determine if a batch is produced correctly, that those records are complete, and that it is appropriate to reprocess a batch. The quality control unit also serves as a quality control check that the batch production record accurately follows the master manufacturing record. A quality control unit review of batch production records could have detected and corrected the previously discussed manufacturing error caused by use of the dietary ingredient with the incorrect selenium. Therefore, the review and documentation by the quality control unit of batch production records provides the necessary quality assurance to prevent the production of an adulterated dietary ingredient or dietary supplement.

Specifically, proposed § 111.50(d) would require your quality control unit to review in accordance with § 111.37(b)(5) the batch production record. If a batch production record deviates from the master manufacturing record, including any deviation from specifications, proposed § 111.50(d)(1) would require your quality control unit to conduct a material review and make a disposition decision and record any decision in the batch production record. Proposed § 111.50(d)(2) would instruct your quality control unit to not approve and release for distribution any batch of dietary ingredient or dietary supplement that does not meet all specifications.

Proposed § 111.50(e) would require your quality control unit to document in accordance with § 111.37(c) the review performed in accordance with proposed § 111.50(d). The proposal would require the quality control unit to document this review at the time it does the review and would require the review and documentation to include, but would not limit them to, the following:

- Review of component, dietary ingredient, and dietary supplement receiving records including review of testing and examination results;
- 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 manufacturing record;
- Records of investigations, conclusions, and corrective actions performed in accordance with proposed § 111.50(d); and
- The identity of the person qualified by training and experience who performed the investigation in accordance with proposed § 111.50(d).

Proposed § 111.50(f) would prohibit you from reprocessing a batch that deviates from the master manufacturing record unless your quality control unit approves it for reprocessing. Proposed § 111.50(f) also would prohibit you from reprocessing a dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms of public health significance or other contaminants, such as heavy metals because you cannot rely on reprocessing to correct public health concerns that a product with pathogens and/or heavy metals would present.

Proposed § 111.50(g) would require that you meet all specifications established in the master manufacturing record for any batch of dietary ingredient or dietary supplement that is reprocessed and would require your quality control unit to evaluate and approve the batch before releasing for distribution. This requirement is intended to ensure that a reprocessed batch is not subject to any lesser specifications than are otherwise applicable to a nonreprocessed batch. Proposed § 111.50(g) also would require that you document the results of the quality control unit's reevaluation in the batch production record.

Proposed § 111.50(h) would require that you collect representative reserve samples of each batch of dietary ingredient or dietary supplement and 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 whether, for example, the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition. Reserve samples also may prove helpful in investigating possible tampering or counterfeiting of your products. We invite comment on whether we should require, in a final rule, that you identify each reserve sample with the batch number so that you can readily identify the correct reserve sample in the event that there is a problem with a particular batch.

Proposed § 111.50(i) would require that you keep your batch production records in accordance with proposed § 111.125. The batch production records in addition to the master manufacturing records will ensure that a complete history of each batch of dietary ingredient or dietary supplement is available for your review in the event that a problem arises with a particular batch. These records also are necessary to demonstrate compliance with the CGMP and quality control procedures.

6. What Requirements Apply to Laboratory Operations? (Proposed § 111.60)

Proposed § 111.60 would establish various requirements for laboratory operations. Proposed § 111.60(a) would require that you use adequate laboratory facilities to perform any necessary tests or examinations to determine that components, dietary ingredients, and dietary supplements you receive meet specifications; that specifications are met during inprocess as specified in the master manufacturing record; and that the dietary ingredients and dietary supplements you manufacture meet their specifications.

One comment to the ANPRM recommended that the regulations related to laboratory operations apply to laboratory facilities located and operated within a company and those facilities that a company may contract with that are located elsewhere. Proposed § 111.60(a) would apply to laboratory facilities generally and is not restricted to laboratory facilities located and operated within a company. In other words, even if you hire a private laboratory to perform various tests for you, proposed § 111.60(a) would require that you make sure that the private laboratory's facilities are adequate to perform whatever tests are necessary. The most important point in proposed § 111.60(a), however, is not where the facility is located, but whether the laboratory facility is adequate for the tests and examinations that need to be done.

Proposed § 111.60(b)(1) would require that you establish and follow laboratory control processes that the quality control unit has approved. For example, under proposed § 111.60(b)(1)(i) and (b)(1)(ii), the laboratory control processes would include use of criteria for selecting appropriate testing and examination methods and for establishing appropriate specifications. Specifications play an important role in CGMP's because they may help

determine whether a dietary ingredient or dietary supplement is adulterated.

Criteria for establishing appropriate specifications must be specific to the component, dietary ingredient, or dietary supplement. The specifications are the parameters that you must meet. For example, for ascorbic acid, your specifications would include all the criteria that you want your incoming dietary ingredient or for your finished product to meet. For example, you might establish criteria for the appearance, color, odor, identity using one or more tests, heavy metals (*e.g.*, lead, arsenic, mercury), and organic volatile impurities.

Similarly, criteria for selecting appropriate test and examination methods include parameters such as type of tests and examinations needed based on the component you receive. For example, you might use morphological characters and organoleptic characteristics in some cases to identify botanical dietary ingredients at the time of collection or for unprocessed botanicals. When sufficient morphological characters are present to separate the plant species from other plant species, an accurate identification can be made since morphological characters are the sole basis of distinguishing most of the world's plant species. However, unprocessed botanicals that do not contain all the plant parts necessary to include adequate morphological characters to assure the correct species should have other identity aids or tests to assure the identity of the botanical. It is possible to use only a picture as an identity standard for whole fresh Ginkgo leaf from a cultivated field because the Ginkgo leaf is not easily confused with the leaf shape, venation, and color of other leaves that could be present in the field. In contrast, powdered Ginkgo leaf is a different form of the dietary ingredient and would require microscopic and/or chemical analysis. Ginkgo extracts have no morphological or anatomical features, and it is possible that extracts may include a number of chemical compounds at different ratios and concentrations that would require a different chemical test to assure the identity of the dietary ingredient. Botanical dietary ingredients that come from wild rather than cultivated sources may grow among and be unintentionally harvested with ''poisonous'' plants; therefore, an identity test also would need to show whether a botanical dietary ingredient is adulterated with another substance or a poisonous plant.

To illustrate this point, a specification may contain a simple identity test, and these tests may show whether a dietary ingredient is adulterated with another substance or is a poisonous plant that should not be ingested. Misidentification or a mixup of botanical ingredients can cause a product to be adulterated (Refs. 6 and 69 through 73). Heavy metals may contaminate botanical and natural-occurring ingredients if a plant is grown and harvested in an area contaminated with heavy metals or even processed in a contaminated area (Refs. 74 and 75). Pesticides also may contaminate botanical ingredients; this occurs in rural areas where the botanical plant grow alongside commercial crops (Ref. 64). Therefore, you must consider what criteria you need to include for the types of testing that are needed, for example, for heavy metal or pesticide contamination, or identity testing criteria for selecting appropriate test methods, for example, whether to use organoleptic or chemical analyses for identity testing. In addition, you must establish criteria for specifications for the tests and examinations used. Establishing such criteria for specifications and appropriate test and examination methods will provide you with internal processes that will help prevent misidentification and contamination.

Proposed § 111.60(b)(1)(iii) would require your laboratory control processes to include use of sampling plans for obtaining representative samples of:

- Components, dietary ingredients, and dietary supplements received;
- Inprocess materials during the batch manufacturing when testing or examination is required in the master manufacturing record;
- Each batch of dietary ingredient or dietary supplement manufactured to determine that the dietary ingredient or dietary supplement meets specifications;
- Packaging and labels received to determine that the materials meet specifications; and
- Each batch of packaged and labeled dietary ingredients or dietary supplements to ensure that the label specified in the master manufacturing record has been applied.

For example, a representative sample is important to being able to have an adequate sample to detect contamination. Contamination may not be distributed evenly throughout a product and may not be detected without a representative number of units. Determining the size of a representative sample is important because the sample size must be large enough to meet your testing needs for specific types of components, dietary ingredients, or dietary supplements, and packaging and labels. Your sampling plans should include reserve samples, too, because reserve samples will enable you to investigate and identify possible manufacturing problems in the future. The proposal would not specify any particular sampling plan; it would leave such details to your discretion so that you can develop a sampling plan that suits your products and your testing needs.

Proposed § 111.60(b)(iv) through (b)(vi) would require the laboratory control processes to include:

- Use of criteria for selecting standard reference materials used in performing tests and examinations. An authenticated plant reference material may be used as standard reference material in performing certain organoleptic examinations. An authenticated plant reference material is material that has been authenticated as the correct plant species and correct plant part(s) by a qualified plant taxonomist. As described earlier in this document, an organoleptic examination may be an appropriate examination to confirm plant identity when sufficient morphological characters are present to separate the plant species from other plant species. For microscopic and chemical tests, a reference material is a highly purified compound that is well characterized, and you would use the reference material to perform tests including calibration tests. In general, there are two types of reference materials: (1) Compendial reference standards that do not require characterization; and (2) noncompendial standards. Noncompendial standards should be of the highest purity that can be obtained by reasonable effort and should be thoroughly characterized to assure their identity, purity, quality, and strength. Ideally, you should use compendial reference standards whenever possible, but if no compendial reference standard exists, you should establish appropriately characterized inhouse materials prepared from representative lots;
- Use of appropriate test method validations. Test method validation determines whether a newly-developed or existing test method is accurate, precise, and specific for its intended purpose. We have discussed previously the terms ''accurate'' and ''precise.'' Validation involves evaluating the test method on multiple occasions or in multiple test facilities. Official methods, such as AOAC International methods, are validated in collaborative studies using several laboratories under identical conditions. The AOAC International methods that are validated

in collaborative studies often are often cited as ''official validated methods.'' If you modify an officially validated method, you should document the reason for the modification and have data to show that the modified method produced results that are at least as accurate and reliable as the established method for material being tested. Further, you should have complete records of any testing and standardization of laboratory reference standards, reagents, and standard solutions that you use in your laboratory operations. Proposed § 111.25(b)(1) would require calibration of laboratory instruments, apparatus, gauges, and recording devices. Validated methods also exist in official compendia for vitamins, minerals, and several botanicals, so you should use validated methods whenever available. You may use validated methods that can be found in official references, such as AOAC International, USP and others. Other method validations are conducted using two or three laboratories or in a single laboratory by repeating the same test multiple times. Official and nonofficial method validations use similar performance parameters in conducting method validations. If an official validated method does not exist in an official reference, the method you use may be validated by using multiple tests at your laboratory or multiple laboratories performing the same test to document that the intended use of the method is consistently fulfilled. You must validate that the official or nonofficial method works under your conditions of use in your setting. You also should conduct day-to-day validations of the method that you use, whether it is an official validated method or a less-formal validated method, under the conditions of use to ensure that the method will provide the information you need to ensure that your dietary ingredient or dietary supplement has the identity, purity, quality, strength, and composition that it is supposed to have and is thus not adulterated. Consistent, day-to-day test recoveries for the reference material are one indicator that the analytical method is working. There are at least two references that describe test method validation performance parameters: (1) Performance parameters for chromatographic methods are described in ''Reviewer Guidance, Validation of Chromatographic Methods'' (Center for Drug Evaluation and Research, FDA, November 1994) (Ref. 76); and (2) International Conference on Harmonisation (ICH); Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (63 FR 31506, June 9, 1998); and

- Use of test methods in accordance with established criteria. Your process for performing test methods criteria must include sufficient detail, including the material you are testing, the purpose of the test, and the test method. The description of the test method criteria must include any reagents used and preparation instructions, apparatus required, any instructions for preparing the sample to be tested, and instructions for conducting the examination. For example, if you receive components of plant origin from an outside source, your specifications must indicate that you test those components to verify that they are not contaminated with adulterants of vegetable origin and to determine that the microscopic examination method is appropriate for use. Further, you may decide that the AOAC International Official Method 961.01 entitled ''Adulterants in Spices'' is the appropriate analytical method to detect the contaminant which is a method to detect adulterants of vegetable origin in spices. Your test methods criteria must specify the component, dietary ingredient, or dietary supplement to be tested, and what specifically to test for, *e.g.*, the identity of the component, dietary ingredient, or dietary supplement, or a specific contaminant. The method criteria must provide detailed information about performing the analysis (*i.e.*, the reagent solutions needed and their preparation, the type of microscope and other equipment required, preparing the sample, and examination instructions). The proposed rule would not require that you test for any specific substance and would not require a specific test for a substance, so you would be able to evaluate what the most appropriate test would be for the component, dietary ingredient, or dietary supplement and to use the test methods that are suited to your products and your manufacturing needs. Your test methodology must be specific for the component, dietary ingredient, or dietary supplement and the specifications you have established.

Proposed § 111.60(b)(2) and (b)(3) would apply to documentation and recordkeeping for your laboratory operations. Proposed § 111.60(b)(2) would require the person who conducts the testing and examination to document, at the time of performance, that they followed the laboratory method and the testing and examination results. Proposed § 111.60(b)(3) would require that you keep laboratory testing and examination records in accordance with proposed § 111.125. Laboratory records are necessary to ensure compliance with established specifications and to demonstrate compliance with the CGMP and quality control processes.

Proposed § 111.60(c) would require that you verify that the laboratory testing methodologies are appropriate for their intended use.

Proposed § 111.60(d) would require that you identify and use the appropriate validated testing method to use for each established specification for which testing is required to determine whether the specification is met. In other words, the proposal would recognize that requiring that you have testing methods is not sufficient alone; you must also use those testing methods to prevent the adulteration of dietary ingredients or dietary supplements.

We invite comment on whether we should require, in a final rule, written procedures for your laboratory operations and should require that the person who performs the laboratory processes document, at the time of performance, that the laboratory processes were performed. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

7. What Requirements Apply to Manufacturing Operations? (Proposed § 111.65)

Proposed § 111.65 would require that you take all necessary precautions to ensure that, during the manufacturing operations, you do not create a source of possible contamination and that specifications are consistently achieved.

Under proposed § 111.65(a), you must design or select equipment and processes to ensure that dietary ingredient or dietary supplement specifications are consistently achieved. Frequently, a computer or system of computers may control many or all stages of manufacturing operations such as mixing, producing tablets, and packaging. It is important that such systems and equipment function as expected to ensure that the dietary ingredient or dietary supplement contains a homogenous mixture, a tablet that is neither too hard or too friable, and that the packaging contains the correct dietary ingredient or dietary supplement. Equipment used in dietary ingredient or dietary supplement manufacture, packaging, and label operations must be, for example, of an appropriate size and installed properly in order to produce an unadulterated product. If not designed or installed properly, the equipment can result in a variety of problems. For example, a mixer for the blending of powdered ingredients will not properly perform its function if the blade is too small relative to the size of the mixer or not properly placed inside of the mixer. Such a mixer may produce an adulterated product because the dietary supplement, for example, is not of uniform composition and therefore would not be able to meet the specifications for purity, quality, strength, or composition in the final product. Thus, equipment design and selection is critical to ensure that you manufacture an unadulterated dietary ingredient or dietary supplement.

Proposed § 111.65(b) would require that you conduct all manufacturing operations in accordance with adequate sanitation principles. We discussed the importance of having adequate sanitation earlier and related it to the use of sanitary practices for employees, physical plant, and equipment.

Proposed § 111.65(c)(1) through (c)(11) would require that you take all the necessary precautions during the manufacture of dietary ingredients and dietary supplements to prevent contamination of components, dietary ingredients, and dietary supplements.

Proposed § 111.65(c)(1) would require that you perform manufacturing operations under conditions and controls that protect against the potential for microorganism growth and the potential for contamination. This would require that you conduct all operations in receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, sorting, and packing dietary ingredients and dietary supplements in accordance with appropriate and established sanitation procedures. Operations with poor sanitation in the production and processing environment can significantly increase the risk of contaminating components, dietary ingredients, or dietary supplements. Pathogenic microorganisms may be found on the floors and in the drains of the processing area and on all contact surfaces. Without good sanitary practices, any surface that comes in contact with components, dietary ingredients, and dietary supplements could be a potential source of microbial contamination. Thus, using appropriate sanitation procedures would provide conditions and controls to protect against potential contamination and microbial growth.

Proposed § 111.65(c)(2) would require that you wash or clean components that contain soil or other contaminants. This is a basic sanitation procedure to protect against contamination and microbial growth. Raw agricultural materials and other components that contain soil or other contaminants must be washed or cleaned as necessary. Water quality used for washing, rinsing, or conveying raw agricultural materials must be adequate for its intended use, both at the start and at the end of the processing operation, and should not contribute to the contamination of such materials.

Proposed § 111.65(c)(3) would require that you use water that meets the EPA's NPDW regulations or, where necessary, higher sanitary quality and that complies with all applicable Federal, State, and local regulations for water that is used in the manufacturing operation. If you reuse water that was used to remove soil or contaminants from components, the proposal would require that the reused water be safe and of adequate sanitary quality so that it does not become a source of contamination. Some manufacturing operations may require water of a higher sanitary quality than water that meets the NPDW regulations. For example, the fluoride or chloride levels in water meeting the NPDW regulations may interfere with certain capsule or tablet operations and a higher quality water such as distilled water may be necessary. This proposed requirement allows the manufacturer discretion in determining whether NPDW regulations or higher sanitary quality water is necessary for a manufacturing operation.

Proposed § 111.65(c)(4) would require that you perform chemical, microbiological, or other testing, as necessary, to prevent the use of contaminated components, dietary ingredients, and dietary supplements. You should consider identifying those areas in the processing and production areas where chemical, microbial, or other forms of contamination are most likely to occur. Chemical, microbial, or other testing is necessary to identify areas where sanitation measures have not been adequate or where products may become adulterated.

Proposed § 111.65(c)(5) would require that you sterilize, pasteurize, freeze, refrigerate, control hydrogen-ion concentration (pH), control humidity, control water activity, or use any other effective means to remove, destroy, or prevent the growth of microorganisms and to prevent decomposition. The measures you decide to use to remove, destroy or prevent the growth of microorganisms on or in your components, dietary ingredients, or dietary supplements must be appropriate under the conditions of manufacture, handling, and distribution. Such measures are necessary to prevent their adulteration and misbranding. Microorganisms include pathogenic bacteria that, if present would adulterate the product. In addition, decomposition may result in a change in the component, dietary ingredient, or dietary supplement strength; the consequence of not using the appropriate measure may be that the dietary ingredient or dietary supplement no longer meets specifications, and thus, would be adulterated under section 402(g) of the act and misbranded under section 403 of the act. By including the phrase, ''any other effective means,'' we provide you with discretion to decide which measures to use to destroy or prevent the growth of microorganisms and to prevent decomposition.

Proposed § 111.65(c)(6) would require that you hold components, dietary ingredients, and dietary supplements that can support the rapid growth of microorganisms of public health significance in a manner that prevents them from becoming adulterated.

Proposed § 111.65(c)(7) would require that you identify and hold any components, dietary ingredients, and dietary supplements, that require a material review and disposition decision, in a manner that protects the components, dietary ingredients, and dietary supplements against

contamination and mixups. A dietary ingredient or dietary supplement under this proposed rule would require a material review and disposition decision when the components, dietary ingredients, or dietary supplements deviate from specifications. As previously explained, the specifications established as production and process controls under proposed subpart E of part 111, are regulatory specifications. Thus, a deviation from such a specification means that the components, dietary ingredients, or dietary supplements may be adulterated. Any component, dietary ingredient, or dietary supplement that may be adulterated must be segregated from such material that meets specifications so that it does not become a source of contamination. The proposal would require that you hold these components, dietary ingredients, and dietary supplements in a manner that protects against contamination and mixups.

Proposed § 111.65(c)(8) would require that you perform mechanical manufacturing steps (such as cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) by any effective means to protect the dietary ingredients or dietary supplements against contamination. Such steps must include consideration of cleaning and sanitizing contact surfaces, using temperature controls, and using time controls. For example, when blending components, if you use a mixer that has not been cleaned and sanitized, your blended material may become contaminated with microorganisms, including microbial pathogens. Thus, it is important to clean and sanitize your mixer before use.

Proposed § 111.65(c)(9) would require that you use effective measures, such as filters, traps, magnets, or electronic metal detectors, to protect against the inclusion of metal or other foreign material in your components, dietary ingredients, or dietary supplements. This proposed requirement is intended to exclude foreign and extraneous matter that would contaminate components, dietary ingredients, or dietary supplements. The purpose of this proposed requirement is not to exclude dietary ingredients that are intended to be used and that are of mineral origin.

One comment to the ANPRM suggested that we require the use of effective measures to protect against the inclusion of metal or other extraneous material in dietary products when there is reason to suspect that the product is contaminated by metal or other extraneous material. The comment stated that manufacturers typically are able to identify the particular piece of equipment that is the source of the metal contamination.

We disagree with the comment. 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. We believe that the most practical way to protect against the inclusion of metal and foreign material is to require that you use effective measures during the manufacturing operations. The source of metal contamination is not limited to equipment and we previously emphasize the need to maintain equipment to prevent such contamination. Metal contamination also may occur during harvesting of natural products and use of utensils such as metal brushes. Therefore, because we believe that it is not possible to identify and eliminate all possible sources of metal contamination or to determine when measures would be necessary to eliminate such contamination, proposed § 111.65(c)(9) would require that you use effective measures to protect against the inclusion of metal and foreign material for all your manufacturing operations.

Proposed § 111.65(c)(10) would require that you segregate and identify all containers for a specific batch of dietary ingredients or dietary supplements to identify their contents and, where necessary, the phase of manufacturing. This proposed requirement is intended to protect ingredients or dietary supplements from potential contamination or misuse during manufacturing or storage. Identifications of these items will enable you to determine accurately the status of all batches of dietary ingredients or dietary supplements during all stages of the manufacturing process, will help to prevent mixups in the addition of components or dietary ingredients to the dietary supplement and will facilitate prompt action if any problems in processing are identified.

Proposed § 111.65(c)(11) would require that you identify all processing lines and major equipment used during manufacturing and to indicate their contents, including the name of the dietary ingredient or dietary supplement and the specific batch or lot number and, when necessary, the phase of manufacturing. The same reasons given for proposed § 111.65(c)(10) apply to this proposed requirement.

Proposed § 111.65(d) would require that you 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. If the material review and disposition decision allows you to reprocess the component, dietary ingredient, or dietary supplement, proposed § 111.65(d) would require that you retest or reexamine it to ensure that it meets specifications and is approved by the quality control unit.

The person who performs the material review and disposition review required in accordance with this section would be required to document at the time of performance the results of the material review and disposition decision. In accordance with § 111.50(d), such documentation must be maintained with the batch production record.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures to implement the manufacturing operations required in proposed § 111.65. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

8. What Requirements Apply to Packaging and Label Operations? (Proposed § 111.70)

Proposed § 111.70 would establish requirements for your packaging and label operations. The correct use of packaging and labels can affect whether your product is adulterated. For example, if a packaging material, intended only for use with a dry product, is used to package a liquid, unsafe substances could migrate from the packaging to the liquid, and adulterate your dietary ingredients or dietary supplements. In addition, if you apply the wrong label, your product would be adulterated under section 402(g) of the act because your label must be that which is specified in the master manufacturing record. In addition, your product would be misbranded under section 403 of the act.

Proposed § 111.70(a) would require that you take necessary actions to ensure each packaging container for holding dietary ingredients or dietary supplements meets its specifications so that the packaging container's condition will not contaminate your dietary ingredients or dietary supplements or cause them to deteriorate. As previously stated in the discussion of proposed § 111.35(e)(4), you must establish specifications for packaging materials that may come in contact with dietary ingredients or dietary supplements. Meeting such specifications would ensure that the packaging that is used is safe and suitable for the intended use and meets all of the statutory and regulatory requirements under the act. In that way, the packaging materials will not adulterate the dietary ingredient or dietary supplement. This proposed requirement would give you the discretion to establish the specifications for each packaging container, and would require that these specifications are routinely met. For example, if your product is sensitive to light, you would choose a container that protects the product from the light so that it does not deteriorate.

Proposed § 111.70(b) would require that you fill, assemble, package, and perform other related operations in a way that protects your dietary ingredients or dietary supplements against adulteration and misbranding. The proposal would require that you use any effective means to do this, which would include:

- Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary ingredient or dietary supplement containers, as appropriate. This is important because cleaning and sanitizing all filling and packaging equipment can help you avoid some common mistakes that can adulterate your products. For example, in one case, a consumer complained about receiving two different sized capsules in a bottle labeled as containing acidophilus capsules. We conducted an investigation and found that the manufacturer had received a similar report from a different consumer (Ref. 77). We analyzed the capsules and found that the smaller capsules were not acidophilus capsules but contained levels of stannous fluoride that would cause convulsions in certain persons and even exceeded the lethal dose in small children. We also collected unopened bottles of the acidophilus product and, after opening the product, found different sized capsules. The presence of smaller capsules containing stannous fluoride mixed in with the larger acidophilus capsules adulterated the product. The fact that these small stannous fluroride capsules mixed in with the larger acidophilus capsules indicated that the manufacturer had not cleaned the filling equipment properly.

In another case, consumer complaints about a vitamin C product prompted us and the product's manufacturer to investigate the product (Ref. 78). We both discovered that the products contained niacin instead of vitamin C, and the problem was the result of a failure to clean out the packaging equipment so that niacin that had been left in the packaging equipment was put into the capsules during the manufacturing operation for the vitamin C product. The manufacturer reviewed its packing operations and instructed its personnel at the manufacturing plant to prevent this problem from reoccurring.

- Protecting manufactured dietary ingredients and dietary supplements from contamination, particularly airborne particulates such as dust, dirt, or microbes that may contaminate your product when your product is exposed to the environment.
- Using sanitary handling procedures.
- Establishing physical or spatial separation of packaging and labels from operations on other dietary ingredients and dietary supplements to prevent mixups. It is important to keep inprocess material separate from finished product that is ready to be packaged and labeled so that inprocess material is not inadvertently packaged and labeled as finished product. In addition, this proposed requirement would prevent mixup of one type of dietary ingredient with another type of dietary ingredient during packaging and label operations such as the vitamin C and niacin mixup described earlier.
- Identifying, by any effective means, filled dietary ingredient or dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups;
- Identifying the dietary ingredient or dietary supplement with a batch, lot, or control number that can be used to determine the manufacturing history and control of the batch. Using a unique identifier for each batch or lot is necessary for you to trace the manufacturing history for a particular batch, and thus help you investigate and correct any safety problems for a batch or to recall a dietary ingredient or dietary supplement batch. For example, if you discovered a particular batch had a safety problem, you could recall the batch by identifying the batch number for the problem product. If you did not have a unique identifier, consumers would be unable to determine which product was the subject of a recall, and they may not stop using the product or you will have to recall more of the product.
- Examining a representative sample of the packaged and labeled dietary ingredient or dietary supplement to ensure that it meets specifications and that the label specified in the master manufacturing record has been applied; and
- Suitably disposing of labels and other packaging for dietary ingredients or dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations. The use of any obsolete or incorrect label would adulterate the product because it would not comply with the requirement that the correct label as specified in the master manufacturing record be used.

Proposed § 111.70(c) would require that you conduct a material review and make a disposition decision of any packaged and labeled dietary ingredients or dietary supplements that do not meet specifications. If packaged and labeled dietary ingredients or dietary supplements do not meet specifications, it means that there is a problem and that the dietary ingredient or dietary supplement may be or is adulterated and this step is needed to determine what to do and how to handle the product to ensure that it does not get distributed.

Sometimes problems arise because a manufacturer used the wrong label on a particular ingredient. For example, in one case, an ingredient manufacturer put the wrong label on its product so that a product labeled as containing zinc picolinate actually contained zinc polynicotinate (Ref. 79). The dietary

ingredient went to another manufacturer who, believing that the product was zinc picolinate, used the dietary ingredient to make its dietary supplement. The error was discovered after consumers who used the product started complaining of adverse reactions that are associated with niacin supplements, but the problem could have been avoided if the dietary ingredient manufacturer had taken steps to ensure that the correct labels were used.

Proposed § 111.70(d) would require that you repackage or relabel dietary ingredients or dietary supplements if approved and appropriately documented by your quality control unit. The quality control unit would need to decide whether the improperly packaged product was adulterated by the incorrect package and could be repackaged and relabeled without reprocessing of the dietary ingredient or dietary supplement.

Proposed § 111.70(e) would require that you retest or reexamine any repackaged or relabeled dietary ingredients or dietary supplements. They must meet all specifications and the quality control unit must approve or reject their release for distribution. The reason this is necessary is to ensure for example, by testing or examination, that the repackaged or relabeled product meets specifications and that the container in which the product is repackaged meets specifications.

Proposed § 111.70(f)(1) would require that you control the issuance and use of packaging and labels and reconcile the issuance and use of discrepancies. It is important to control access to the storage of packaging and labels; for example, only the labels that are required for current label operations should be issued to prevent issuance of any incorrect labels during the label operation. Using batch or lot numbers on your labels may be one control method. Batch or lot numbers also help you (and us) to identify a particular product and to trace that product's manufacturing history through your CGMP records. They can help identify which products are affected by a product recall, if a recall is necessary, and this can help preserve consumer confidence in your product.

For example, if a recall covers batch A123, and a particular consumer has a product whose batch number is C456, he or she will know that the product is not covered by the recall. In contrast, if no batch numbers appear on the product label, the consumer would not be able to tell whether his or her product is covered by the recall and may continue to use it.

As another example, controlling access of labels can help identify instances when mislabeling may have occurred. If you issue only the necessary number of labels to cover a particular production run but use fewer labels than expected even though you labeled the expected number of containers for the production run, this discrepancy would suggest that you used some wrong labels during the run and that you should conduct an investigation to determine the cause of, or reconcile the discrepancy.

Proposed § 111.70(f)(2) would require that you must examine carefully, before packaging operations, packaging and labels for each batch of dietary ingredient or dietary supplement to ensure that the label and packaging conform to the master manufacturing record.

Proposed § 111.70(g) would require that the person who performs the requirement established in accordance with this section document, at the time of performance, that he or she performed the requirement. This would include, but not be limited to, documentation in the batch production record of:

- The identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use;
- The examination of a representative sample (as proposed § 111.70(b)(7) would require);
- The conclusions you reached from retests conducted under proposed § 111.70(e); and
- Any material reviews and disposition decisions for packaging and labels.

Proposed § 111.70(h) would require that you keep the packaging and label operations records required under this section established in accordance with proposed § 111.125. These records are necessary to ensure that the correct packaging and label, *i.e.*, the packaging and label specified by the master manufacturing record, were used in and applied to the batch of dietary ingredient or dietary supplement. These records together with the master manufacturing records and batch production records will ensure that a complete history of each batch of dietary ingredient or dietary supplement including use of the correct packaging and label is available for your review in the event that a problem arises with a particular batch. These records also are necessary to demonstrate compliance with the CGMP and quality control procedures. We invite comment on whether we should require, in a final rule, that you establish and follow written procedures for packaging and label operations that implement the requirements of this section. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength and composition of the dietary ingredient or dietary supplement. Further, we seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

9. What Requirements Apply to Rejected Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels? (Proposed § 111.74)

Proposed § 111.74 is intended to ensure that you do not mistakenly use rejected materials that are determined by the quality control unit to be unsuitable for use to make a dietary ingredient or dietary supplement.

Proposed § 111.74(a) 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. The term ''control under a quarantine system'' indicates that you must prevent the use of any rejected component, dietary ingredient, dietary supplement, packaging, or label because such rejected product is unsuitable for use. For example, under this proposed rule, if a component, dietary ingredient, or dietary supplement is rejected and determined by the quality control unit

to be unsuitable for use, such material would be adulterated and not be suitable for reprocessing. Therefore, to prevent contamination of nonrejected material, you must quarantine the rejected material before disposal. The proposed rule would not specify any particular mechanism for how you quarantine the material, instead, you would have discretion in deciding what actions to take or what process to use.

You also should note that, by referring to items that are rejected and unsuitable for use, proposed § 111.74(a) excludes items that can be reprocessed and made suitable for use. Those items that can be reprocessed and made suitable for use are dealt with in proposed § 111.82.

*F. Holding and Distributing (Proposed Subpart F)*

1. What Requirements Apply to Holding Components, Dietary Ingredients, Dietary Supplements, Packaging, and Labels? (Proposed § 111.80)

Proposed § 111.80 would require that you hold dietary ingredients and dietary supplements under conditions that will protect them against contamination and deterioration. Proposed § 111.80(a) 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. This proposed provision includes the holding of components, dietary ingredients, dietary supplements in your physical plant and at any point in the distribution process, however, we would not extend the holding requirements under this proposed CGMP regulation to retail establishments, but would defer to State and local governments for regulating operations that provide dietary supplements to retail for sale to the consumer. However, if a retail holding area is filthy, we would not be prevented from taking an enforcement action under a legal authority other than section 402(g) of the act.

This requirement would ensure that products are not contaminated while they are held by the manufacturer, the wholesaler, or while being held at a warehouse. This would increase the likelihood that the products consumers purchase have the same quality as when they left the manufacturer. Note that proposed § 111.80(a) uses the words ''not affected;'' this means that the conditions under which you hold components, dietary ingredients, and dietary supplements must not adulterate the components, dietary ingredients, or dietary supplements. For example, dried plants stored in a hot, humid warehouse may become moldy. Mold contamination could adversely affect the purity of the dietary ingredients and dietary supplements you manufacturer. You will decrease the chances of mold contaminating your dried plants if you control temperature and humidity.

Proposed § 111.80(b) would require that you hold packaging and labels under appropriate conditions of temperature, humidity, and light so that the quality of the packaging and labels are not affected. For example, some plastics become brittle when exposed to extreme temperatures. If brittle plastic containers are used to hold dietary ingredients or dietary supplements, they could crack or break, thereby losing their protective qualities, and lead to contamination or deterioration of the dietary ingredient or dietary supplement. You need to know the conditions of temperature, humidity, and light that are appropriate for your packaging and labels and you need to hold the packaging and labels under such conditions.

Proposed § 111.80(c) would require that you hold components, dietary ingredients, dietary supplements, packaging, and labels under conditions that do not lead to mixup, contamination, or deterioration of the components, dietary ingredients, dietary supplements, packaging, and labels. For example, your holding conditions must include a system for identifying container contents and its status (*e.g.*, segregated, approved for use) in a manner that prevents mixup or use of unsuitable materials in manufacturing. Further, the presence of rodents in your holding area may cause contamination or deterioration of components, dietary ingredients, dietary supplements, packaging, and labels. Therefore, your holding conditions must be rodent-free. Moreover, rodents in your holding area would adulterate your dietary ingredient or dietary supplement under section 402(g) of the act. Holding conditions that prevent mixup, contamination, or deterioration of components, dietary ingredients, dietary supplements, packaging, or labels are necessary to prevent the production of an adulterated dietary ingredient or dietary supplement.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures for holding components, dietary ingredients, dietary supplements, packaging, and labels. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

2. What Requirements Apply to Holding Inprocess Material? (Proposed § 111.82)

Proposed § 111.82 discusses proposed requirements for holding inprocess material. Proposed § 111.82 would require that you segregate any inprocess material that does not meet your specifications, is awaiting further processing, or needs further evaluation by the quality control unit (*e.g.*, because the inprocess material does not meet specifications, or because of an unexpected occurrence) to determine if it is suitable for reprocessing.

Proposed § 111.82(a), therefore, would require that you identify and hold inprocess material under conditions that will protect such material against mixup, contamination, and deterioration.

Proposed § 111.82(b) would require that you hold inprocess material under appropriate conditions of temperature, humidity, and light. The intent here is to prevent any contamination or deterioration of that inprocess material.

We invite comment on whether we should require, in a final rule, that you establish and follow written procedures for holding inprocess material. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

3. What Requirements Apply to Holding Reserve Samples of Components, Dietary Ingredients, and Dietary Supplements? (Proposed § 111.83)

Earlier, we discussed a provision concerning the collection of reserve samples. Proposed § 111.50(h) would require that you collect representative reserve samples of each batch of dietary ingredient or dietary supplement. Proposed § 111.83 would set forth requirements for holding any reserve samples collected.

Proposed § 111.83(a) would require that you hold any reserve samples of components or dietary ingredients collected in a manner that protects against contamination and deterioration.

Proposed § 111.83(b) would require that you hold such reserve samples of dietary supplements in a manner that protects against contamination and deterioration. Further, this provision would require that you hold the 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. This proposed requirement also would require that you use the same container-closure system in which the dietary supplement is marketed or one that provides the same level of protection against contamination or deterioration as the marketed container-closure system. It is necessary to hold the reserve sample of a dietary supplement under the same conditions and in the same packaging as you would expect a consumer to hold that dietary supplement so that, if you need to later test that reserve sample, the testing would reflect current conditions under which the dietary supplement is held by the consumer prior to being consumed.

4. What Requirements Apply to Returned Dietary Ingredients or Dietary Supplements? (Proposed § 111.85)

Proposed § 111.85 would establish requirements for returned dietary ingredients or dietary supplements. ''Returned'' dietary ingredients or dietary supplements are those products that a distributor, wholesaler, or retailer returns to a manufacturer. Proposed § 111.85(a) would require that you identify returned dietary ingredients or dietary supplements and to quarantine them until your quality control unit conducts a material review and makes a disposition decision. (Your quality control unit would do this under proposed § 111.37.) For example, you could attach a tag or other identifier on the returned dietary ingredient or dietary supplement to show that it is ''returned.'' We would require that you identify and quarantine (not just identify and segregate) returned dietary ingredients or dietary supplements so that they cannot be used. We propose to require that you quarantine returned products because you must assume that the returned product is adulterated until tests show otherwise. Thus, the product should not have physical closeness or contact with nonreturned product to ensure that it will not be mixed up mistakenly with nonreturned product, redistributed or reused in manufacturing.

Proposed § 111.85(b)(1) states that you may salvage returned dietary ingredients and dietary supplements only if:

- 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. This would require that you have personal knowledge of the exact conditions under which the returned dietary ingredients or dietary supplements were held. Normally, for most types of packaging, simply examining the packaging will not tell you about the storage conditions that existed. However, we are aware of some technologies that are being used, such as temperature-sensitive materials that change colors, that could provide some information about storage conditions; and
- Tests demonstrate that the dietary ingredients or dietary supplements meet all specifications for identity, purity, quality, strength, and composition. This requirement will ensure that you do not return to distribution a dietary ingredient or dietary supplement that does not meet specifications. Salvage is available for only those products for which testing can be performed on finished product.

For purposes of this discussion, ''salvage'' means to return to distribution without reprocessing the dietary ingredient or dietary supplement.

Proposed § 111.85(c) would require that you destroy or suitably dispose of the returned dietary ingredients or dietary supplements if they do not meet specifications for identity, purity, quality, strength, and composition, unless the quality control unit conducts a material review and makes a disposition decision to allow reprocessing.

Proposed § 111.85(d) would require that you conduct an investigation of your manufacturing processes and those other batches if the reason for a dietary ingredient or a dietary supplement being returned implicates other batches. The point of the investigation would be to determine whether, for example, the other implicated batches may have the same problem or have been subject to the same problematic manufacturing process for which the dietary ingredient or dietary supplement was returned. Other batches may be implicated if the component or dietary ingredient used in the returned product also was used in additional batches or if your investigation indicates that there was a problem with a step in the manufacturing process that affected additional batches. The proposal also would require that you document the investigation and include your conclusions and followup.

Proposed § 111.85(e) would require you to establish and keep records for any material review and disposition decision and any required testing to determine compliance with specifications done for any returned dietary ingredient or dietary supplement. You should include the following information in your records:

- The name of the person or company or both the name of the person and company who returned the dietary ingredients or dietary supplements;
- A description of the returned dietary ingredient or dietary supplement;
- The batch or lot number of the returned dietary ingredient or dietary supplement and any reprocessed batch or batch manufactured using the returned dietary ingredient or dietary supplement;
- The reason for the return;
- The quantity returned;
- The disposition of the dietary ingredient or dietary supplement; and
- The date of disposition.

Proposed § 111.85(f) would require that you make and keep records for returned dietary ingredients and dietary supplements in accordance with § 111.125. These records are necessary to ensure that returned products that could be adulterated are not inadvertently redistributed or inadvertently used in manufacturing. Further, records of any reprocessed batch or batch manufactured using the returned product will be useful in the event that a problem arises with a particular batch that is manufactured with returned product. These records also are necessary to demonstrate compliance with the CGMP and quality control procedures. We invite comment on whether we should require, in a final rule, that you establish and follow

written procedures for identifying, quarantining, and salvaging returned dietary ingredients and dietary supplements. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

5. What Requirements Apply to Distributing Dietary Ingredients or Dietary Supplements? (Proposed § 111.90)

Proposed § 111.90 would establish requirements concerning the distribution of dietary ingredients and dietary supplements. Proposed § 111.90(a) would require any distribution of dietary ingredients or dietary supplements to be under conditions that will protect them from contamination and deterioration. This is to protect dietary ingredients and dietary supplements from distribution practices that may adulterate them.

As discussed previously, proposed part 111 also would apply to foreign firms that manufacture, package, or hold dietary ingredients and dietary supplements that are imported or offered for import into the United States, unless imported for further processing and export under section 801(d)(3) of the act. It also would apply to persons who distribute imported dietary ingredients and dietary supplements, and to persons who export dietary ingredients and dietary supplements from the United States unless exported in compliance with section 801(e) of the act.

We recognize that the safety of dietary supplements cannot be adequately ensured if the imports are not subject to the same controls as domestic products. In addition, we believe that the importer who distributes a foreign product should share responsibility with the foreign manufacturer for safety. More often than not, it is a U.S. importer, rather than the foreign manufacturer, who actually distributes imported dietary supplements for sale in the United States. Thus, we believe that importers of dietary ingredients or dietary supplements should take steps to ensure that their shipments are obtained from manufacturers that follow these proposed CGMP requirements.

In addition, these proposed CGMPs would apply to manufacturers who export their dietary ingredient or dietary supplement, unless exported in compliance with section 801(e) of the act. Section 801(e)(1) of the act states that a food intended for export must not be deemed to be adulterated or misbranded under the act if it:

- Accords to the foreign purchaser's specifications;
- Is not in conflict with the laws of the country to which it is intended for export;
- Is labeled on the outside of the shipping package that it is intended for export; and
- Is not sold or offered for sale in domestic commerce.

Dietary ingredients and dietary supplements for export are subject to section 801(e)(1) of the act and would be subject to the notification and recordkeeping requirements of § 1.101 (21 CFR 1.101) and you would be required to comply with the export requirements of § 1.101.

We invite comment on whether we should require, in a final rule, that you make and keep records on the distribution of dietary ingredients and dietary supplements that you manufacture, package, or hold.

*G. Consumer Complaints—What Requirements Apply to Consumer Complaints? (Proposed Subpart G, § 111.95)*

Proposed § 111.95 would establish requirements for receiving and handling consumer complaints. Consumer complaints can be helpful in alerting you to possible manufacturing and safety problems associated with your dietary ingredients or dietary supplements.

As stated in § 111.3, consumer complaint refers to a possible failure of a dietary ingredient or dietary supplement to meet any of the requirements of this part, including those that, if not met, may result in a possible risk of illness or injury. Proposed § 111.95(e) would require that you keep a written record of every consumer complaint that is related to good manufacturing practices. Thus, whether the complaint was sent by regular mail, electronic mail, or any other form of written communication, or whether received orally, you would be required to keep a written record of each consumer complaint. You should include all information that would allow your quality control unit to determine whether an investigation of the complaint is necessary.

Proposed § 111.95(a) would require that you have a qualified person review all consumer complaints to determine whether the consumer complaint involves a possible failure of a dietary ingredient or 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 possible risk of illness or injury. A ''qualified person'' would be a person who has the training and experience to determine whether a complaint represents a possible failure of a dietary ingredient or dietary supplement to meet any of the requirements in this part, or represents a possible risk of illness or injury that is unrelated to such failure. The qualified person's review is important for distinguishing between those consumer complaints that your quality control unit must review and those consumer complaints that represent a consumer's dissatisfaction with a dietary ingredient or dietary supplement that is unrelated to a possible failure to meet specifications that would be required by this proposal, or any other requirement in this part. For example, some consumer complaints about quality may simply express a personal dislike of the taste, color, odor, or size of tablet, which would probably not require your quality control unit to review them. As stated earlier, consumer complaints related to an illness or injury related to a pharmacologically active substance of a particular dietary ingredient, such as aristolochic acid, would not be a consumer complaint within the meaning of that term in this proposal and thus would not be of the type that the quality control unit must review under this proposed rule.

Proposed § 111.95(b) would require that your quality control unit review all consumer complaints involving the possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any of the other requirements in this part, including those specifications and other requirements that, if not met, may result in a possible risk of illness or injury, to determine whether there is a need to investigate the consumer complaint. When there is a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event, such as a report of an illness or injury that may be due to a wrong ingredient or wrong label, then the manufacturer would be required to do an investigation that includes both batch records associated with the

dietary ingredient or dietary supplement involved in the consumer complaint. However, if the quality control unit determines that an investigation is unnecessary, it would be helpful to you if your quality control unit documents why an investigation was not necessary. This information would be useful to you because it could save time if you receive additional similar consumer complaints about a particular product.

Proposed § 111.95(c) would require that your quality control unit investigate a consumer complaint when there is a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event. For example, if a manufacturer uses too much of a dietary ingredient in a dietary supplement (*e.g.*, 400 to 4,699 µg of selenium instead of 200 µg of selenium), it is a manufacturing error that may result in an adverse event. Further, if a communication alleges consumer dizziness, vomiting, or lightheadedness after consuming several dietary supplements, it is a adverse event report that is worthy of quality control unit investigation.

Proposed § 111.95(d) would describe what the quality control unit's investigation must include. In brief, the quality control unit's investigation of a consumer complaint must include the batch records associated with the dietary ingredient or dietary supplement involved in the consumer complaint. The quality control unit must extend the investigation to other batches of dietary ingredients or dietary supplements that may have been associated with a failure to meet a specification or any other requirements of this part. When there is a possible product defect or failure, we recommend that the investigation include laboratory testing of the dietary ingredient or dietary supplement because you will need the test results to determine if specifications or requirements for the dietary ingredient or dietary supplement were not met. Complaints such as those that involve serious adverse events should include followup by a health care provider. For other types of complaints, neither laboratory nor medical investigation may be necessary because the product defect or failure may be identified by reviewing batch documents or the consumer complaint may not involve a serious adverse event.

Proposed § 111.95(e) 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 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. The consumer complaint written record must include, but is not limited to, the following:

- The name and description of the dietary ingredient or dietary supplement;
- The batch or lot number of the dietary supplement, if available;
- The complainant's name, if available;
- The nature of the complaint, including how the consumer used the product;
- The reply to the complainant, if any; and
- Findings of the investigation and followup action taken when an investigation is performed.

We suggest that you report the consumer complaint and the investigation results to us when there is a possibility of a relationship between the consumption of a dietary supplement and a serious adverse event. While the proposal would not require that you submit these reports, we strongly suggest that you do so because 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. We suggest that you submit these reports within 15 days after you receive such information to the FDA MedWatch program by calling our ''MedWatch'' program (our database for reporting possible adverse events) at 1–800–FDA–1088 (1–800–332–1088) to request that a reporting form (one-page, return postage paid) and instructions on how to complete the form be mailed to you, downloading a form and instructions from the MedWatch Internet site at *http://www.fda.gov,* or using the interactive form available on the MedWatch Internet site at *http://www.fda.gov.*

Further, we suggest that you report a consumer complaint even if you are not the manufacturer of a dietary ingredient or dietary supplement and only package or distribute a dietary ingredient or dietary supplement if you receive a consumer complaint that may be related to the manufacture of the dietary ingredient or dietary supplement. Sometimes consumers submit complaints to the person who distributes a product or the person who is listed on the package label. If this happens, you should notify the manufacturer of the dietary ingredient or dietary supplement of the consumer complaint because the manufacturer may not be aware of possible problems associated with its products.

Proposed § 111.95(f) addresses documentation and recordkeeping. Consumer complaints can alert you (and us) to potential quality problems with a product that is related to good manufacturing practices, such as cases where the manufacturer used the wrong ingredient or put the wrong label on a product. A prudent manufacturer, therefore, must investigate any complaints regarding its products because the results of its investigations might lead to solutions or improvements that will make the product or manufacturing process better and benefit the manufacturer and consumers.

Proposed § 111.95(f)(1) would require the person who performs the requirement established in accordance with this section to document, at the time of performance, that he or she performed the requirement.

Finally, proposed § 111.95(f)(2) would require that you keep consumer complaint records established in accordance with proposed § 111.125. These records are necessary for handling consumer complaints in a manner that ensures that an unanticipated problem with a dietary ingredient or dietary supplement is reviewed and investigated. These records also are necessary to demonstrate compliance with the CGMP.

We invite comment on whether we should require, in a final rule, that you establish and follow a written procedure for receiving, reviewing, and investigating consumer complaints. 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 ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

### *H. Records and Recordkeeping—What Requirements Apply to Recordkeeping? (Proposed Subpart H, § 111.125)*

Throughout this discussion of the proposed rule, some provisions have included a paragraph that would require

that you keep records established in accordance with proposed § 111.125. Proposed § 111.125 would establish general recordkeeping requirements and tell you how long you must keep certain records. As we have stated several times in this document, we determine CGMP compliance by conducting inspections. Records, therefore, enable you to show, and for us to determine, how you complied with the CGMP requirements.

Proposed § 111.125(a) would apply to all records covered by the proposed rule and would require that you keep those records for 3 years beyond the date of manufacture of the last batch of dietary ingredients or dietary supplements associated with those records. Retention for 3 years beyond the date of manufacture would be appropriate for followup of consumer complaints received during the marketing period.

Proposed § 111.125(b) would deal with the form in which you keep records. The proposal would allow you to keep records required under this part as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. If you use reduction techniques, such as microfilming, the proposal would require that you make suitable reader and photocopying equipment readily available to us. If you use electronic records, the proposal would require that you comply with part 11 (our requirements for electronic records).

Proposed § 111.125(c) would require that you make your records available for inspection and copying by us when requested. We sometimes need to copy records when our field inspectors need guidance or additional expertise from our headquarters staff; if we were unable to copy records, our inspections would become more complicated and longer in duration, particularly if the inspection involved a complex scientific or technical issue that normally would be handled at FDA headquarters.

## IV. Statement Concerning the Use of Plain Language

In response to the June 1, 1998, White House Presidential Memorandum on Plain Language, we drafted this proposed rule in plain language. Plain language is intended to help readers find requirements quickly and understand them easily. To do that, we have reorganized sections modeled after existing regulations and reworded the paragraphs using:

- Short sections, paragraphs, sentences, and words to speed up reading and enhance understanding;
- Sections as questions and answers to focus sections better; and
- Personal pronouns to reduce passive voice and draw readers into the text.

In some cases, we modeled a proposed provision after an existing regulation, but wrote the proposed rule using plain language techniques. We invite the public to comment on the plain language techniques used in this proposed rule. In developing your comments, please consider addressing the following points:

- Do you like the proposed rule's appearance?
- Do plain language techniques make the document easier to read and understand? and
- Do you have other suggestions to improve the format?

## V. Paperwork Reduction Act of 1995

This proposed 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). A description of these requirements is given below 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.

*We invite comments on:* (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed 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 the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Current Good Manufacturing Practice in Recordkeeping and Reporting for Dietary Ingredients and Dietary Supplements.

*Description:* Section 402(g) of the act gives us explicit authority to issue a rule regulating conditions for manufacturing, packaging, and holding 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.'' Other relevant legal authority is discussed in section II of this document.

For this proposed CGMP rule for dietary ingredients and dietary supplements, recordkeeping is necessary to provide the type of documentation that would demonstrate that dietary ingredients and dietary supplements are manufactured, packaged, and held under the conditions that would be required under the proposed CGMP regulations. Under section 701(a) of the act, we may issue regulations necessary for the efficient enforcement of the act. If you did not keep records, for example, documenting practices performed during previous production runs, it would be difficult for us to determine whether, as stated under section 402(g)(1) of the act, the dietary supplement had been manufactured, packaged, and held under CGMPs. By requiring records, we will be able to ensure that you follow CGMPs and that your dietary supplements are not adulterated and misbranded during manufacturing, packaging, or holding operations.

The proposed rule would establish the minimum manufacturing practices necessary to ensure that dietary supplements are manufactured, packaged, or held in a manner that will not adulterate and misbrand the dietary ingredients or dietary supplements.

The proposed regulations would impose requirements for: (1) Personnel, (2) physical plants, (3) equipment and utensils, (4) production and process controls, (5) holding and distributing, (6) consumer complaints, and (7) records and recordkeeping.

We are proposing recordkeeping requirements that include records pertaining to: (1) Calibration of instruments and controls; (2) automatic, mechanical, or electronic equipment calibration, inspection, or checks; (3) production and process controls; (4) quality control; (5) receiving components, dietary supplements, packaging, and labels; (6) master manufacturing and batch production; (7) packaging and label operations; (8) returned dietary ingredients or dietary supplements; and (9) consumer complaints.

*Description of Respondents:* Dietary ingredient manufacturers, dietary supplement manufacturers, packagers and repackagers, distributors, warehousers, exporters, importers, large businesses, and small businesses.

We estimate the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Section | Number of recordkeepers | Annual frequency of recordkeeping | Total annual records | Hours per record | Total hours |
|---|---|---|---|---|---|
| 111.15(b)(3) | 231 | 12 | 2,772 | 0.1 | 277 |
| 111.15(d)(3) | 231 | 260 | 60,060 | 0.25 | 15,015 |
| 111.25(d) | 213 | 365 | 77,745 | 0.5 | 38,873 |
| 111.30(b)(2) and (b)(5) | 707 | 260 | 183,820 | 0.5 | 91,910 |
| 111.35(d) | 10 | 1 | 10 | 10 | 100 |
| 111.35(e) | 367 | 260 | 95,420 | 0.25 | 23,855 |
| 111.35(f) | 367 | 260 | 95,420 | 0.1 | 9,542 |
| 111.35(i)(1) | 367 | 10 | 3,670 | 0.25 | 918 |
| 111.35(j) | 367 | 260 | 95,420 | .25 | 23,855 |
| 111.35(m) | 367 | 365 | 133,955 | 0.1 | 13,396 |
| 111.37(b)(1), (b)(3) through (b)(5), (b)(7) through (b)(10), and (b)(12)(i) | 286 | 260 | 74,360 | 0.5 | 37,180 |
| 111.37(c) | 286 | 365 | 104,390 | 0.5 | 52,195 |
| 111.40(a)(3), (a)(4), (b)(2), and (b)(3) | 449 | 365 | 163,885 | 0.1 | 16,389 |
| 111.40(c)(1) | 218 | 365 | 79,570 | 0.5 | 39,785 |
| 111.45(a) [2] and (b) [2] | 200 | 1 | 200 | 30 | 6,000 |
| 111.50(a) through (c), (d)(1), and (e) | 68 | 260 | 17,680 | 1 | 17,680 |
| 111.50(g) | 68 | 260 | 17,680 | 0.5 | 8,840 |
| 111.60(b)(2) | 133 | 365 | 48,545 | 1 | 48,545 |
| 111.60(d) [2] | 133 | 1 | 133 | 3 | 399 |
| 111.65(c)(7), (c)(10), and (c)(11) | 133 | 365 | 48,545 | 0.1 | 4,855 |
| 111.70(b)(5) through (b)(6), (d), and (e) | 245 | 260 | 63,700 | 0.1 | 6,370 |
| 111.70(g) | 245 | 260 | 63,700 | 0.50 | 31,850 |
| 111.74(a) | 200 | 12 | 2,400 | 0.1 | 240 |
| 111.82(a) | 53 | 52 | 2,756 | 0.1 | 276 |
| 111.85(a) | 53 | 260 | 13,780 | 0.1 | 1,378 |
| 111.85(d) and (e) | 53 | 260 | 13,780 | 0.5 | 6,890 |
| 111.95(e) | 53 | 75 | 3,975 | 0.1 | 398 |
| 111.95(f)(1) | 93 | 75 | 6,975 | 0.5 | 3,488 |
| 111.125 | 220 | 4 | 880 | 0.1 | 88 |
| Total | | | | | 500,587 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.

The burden estimates above are based on our institutional experience with CGMP requirements for drugs and on data provided by Research Triangle Institute (RTI) in the ''Survey of Manufacturing Practices in the Dietary Supplement Industry'' (Refs. E1 and E2). We tentatively conclude that there are no capital costs or operating costs associated with this proposed rule. However, we invite comments on information provided in table 1 of this document or on any anticipated costs.

The estimates for number of firms affected by each provision of the rule are based on the percentage of manufacturers, ingredient suppliers, repacker/relabelers, distributors, and warehousers that reported to RTI that they have not established or do not maintain records that would be required or recommended under the proposed rule. The RTI survey estimated that 1,566 firms would be covered by this rule including manufacturers, dietary ingredient suppliers, repacker/relabelers, 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 260 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, *e.g.*, proposed § 111.50, ''What requirements apply to establishing a batch production record?'' The estimate of 260 batches per year is near the midpoint of the number of annual batches reported by RTI survey firms.

Proposed § 111.125 prescribes the length of time for which CGMP records must be maintained. The burden chart reflects the estimated annual burden for record maintenance, for periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that would be required under part 111. To avoid double-counting, we have not included a separate estimate of burden for those sections that would require maintaining records in accordance with proposed § 111.125, but have included a single burden estimate for all such records maintenance under proposed § 111.125. For example, proposed § 111.50(a) would require that the batch production records be prepared every time a batch is manufactured and § 111.50(i) would require that batch production records be kept in accordance with proposed § 111.125. The estimated burden for establishing the batch production records is counted in proposed § 111.50(a) and the estimated burden for keeping the batch production records as would be required in accordance with § 111.50(i) is counted in proposed § 111.125.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this proposed rule to OMB for its review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (*see* **ADDRESSES**).

## VI. Environmental Impact Considerations

The agency has determined under 21 CFR 25.30(j) 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. Analysis of Impacts

### *A. Introduction*

FDA has examined the economic implications of this proposed rule as required by 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 anyone 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 proposed rule, if it were to become a final rule, would be a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 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 proposed rule, when final, will be a major rule for the purpose of congressional review.

FDA has examined the economic implications of this proposed 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. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities.

We carry out the cost-benefit analyses required for significant rules in the Preliminary Regulatory Impact Analysis, in section VII.B of this document. We perform the Initial Regulatory Flexibility Analysis of the effects on the proposed rule on small businesses in section VII.C of this document.

### *B. Preliminary Regulatory Impact Analysis*

#### 1. The Need for the Proposed CGMP Regulations

The proposed CGMP regulations are needed because establishments that manufacture, package, and hold dietary ingredients and dietary supplements may not have sufficient market incentives to use controls to prevent the adulteration and misbranding of dietary ingredients or dietary supplements, including incentives to ensure their identity, purity, quality, strength, and composition (product quality). Manufacturing, packaging, and holding practices that ensure product quality can be costly, so establishments may not adopt them unless required to do so by regulation. Without the proposed regulations consumers of dietary supplements cannot be assured that all establishments are manufacturing dietary supplements in a way that ensures that these products are not adulterated or misbranded.

Manufacturing, packaging, and holding practices can compromise safety if they fail to prevent biological, chemical, and physical contamination, or if the wrong dietary ingredients are used that present an unreasonable risk of illness or injury. Strength (which is the amount of a specific dietary supplement or dietary ingredient in each tablet or capsule) that differs from label statements, missing or extra ingredients, and inconsistency across units of the product are other problems caused by poor manufacturing practices. Products may also be held in insanitary or environmentally inappropriate conditions, or may be physically damaged if stored improperly. Some poor manufacturing practices, such as the use of ingredients that are undeclared, of incorrect strength, or missing altogether result in a misbranded product. The proposed CGMP regulations would establish minimum requirements to ensure that manufacturing, packaging, and holding practices ensure the identity and quality of components, dietary ingredients, and dietary supplements.

Consumers today rely on manufacturer's assurances, existing regulations and statutes (for example, section 402(a)(3) and (a)(4) of the act), and recourse to the legal system to ensure that products are not defective. Brand names convey some information to consumers about a firm's manufacturing practices. Some private organizations, such as the National Nutritional Foods Association and the USP design minimum product standards or manufacturing requirements. The current act contains some provisions that prevent using putrid substances and insanitary manufacturing practices. In addition, either the threat of litigation or consumers seeking compensation for defective products and adverse health events may create incentives for establishments to adopt good manufacturing practices.

Actions by manufacturers, primarily voluntary quality controls, do not provide sufficiently protective industry-wide minimum requirements for manufacturing, packaging, and holding of dietary ingredients and dietary supplements. Without the proposed regulations, survey evidence shows that products in the dietary supplement market are sorted somewhere between two types:

- Higher-priced products with brand names or industry certification that follow several of the good manufacturing practices proposed here;
- Lower-priced products that contain no private certification or respected brand name and that follow few of the good manufacturing practices that are proposed here.

Without the proposed rule, the current practices do not provide all consumers with safe manufacturing practices or reliable product quality throughout the industry.

The market for dietary supplements is full of information; consumers of dietary supplements must sort through information and misinformation about the properties of these products from magazines, brochures, popular books, television, and a host of other sources. However, the information from these sources deals most often with the claims for the products themselves, not with the steps taken by establishments to protect against contamination or to ensure quality. Private quality control fails to provide industry-wide minimum good manufacturing practices for the following reasons:

- Establishments do not have incentives to disclose information about their own practices, because disclosure that some consumers may perceive to be harmful or undesirable would reduce the demand for their products. Establishments therefore have incentives to withhold information from consumers.
- Businesses normally do not advertise differences in manufacturing

practices. They seldom have access to competitors' proprietary information, and they may fear that advertising based on differences in practices would discredit the entire industry.

• Without public disclosure of product quality and adverse health events, the link between manufacturing practice and health hazard is difficult to establish. The link is probabilistic, requires data pooling across products and establishments (in order to establish cross sectional variation), and can be interpreted in a variety of ways.

• Because many consumers already mistakenly believe that the Federal Government guarantees safety, businesses have weak incentives to adopt good manufacturing practices, which are costly. In one recent survey of the nation's consumers, 34 percent report that they believe that the government regulates dietary supplements to ensure safety and that products do what they claim to do. (For details of the survey, *see* Ref. E3.) If people believe that good manufacturing practices are already followed, manufacturers may believe they gain little from voluntarily adopting them.

Information about manufacturing practices for dietary supplements is imperfect and costly to produce, so well-informed people should be willing to pay for improvements in the quality of information. An important benefit of the proposed regulations will be to reduce variation in manufacturing practices and ensure minimum quality for dietary supplement products. Reducing the variation in product quality by creating industry-wide minimum requirements reduces the information consumers now attempt to get through costly and uncertain sources in order to make purchasing decisions.

2. Regulatory Options

FDA considered several regulatory options for dealing with current manufacturing, packaging, and holding practices that may not ensure product quality. The options considered include: (a) No new regulatory action, (b) fewer requirements for vitamins and minerals, (c) more restrictive regulations than the proposed CGMP regulations, (d) HACCP without the other elements of CGMP regulations, (e) final product testing only, (f) regulations for high-risk products or hazards only, and (g) the proposed rule.

a. *No new regulatory action.* Under this option, consumers would probably rely on the following as protection against defective products:

• Possible enforcement action by FDA under, for example, section 402(a)(3) and (a)(4) of the act, regarding adulterated foods that consist of filthy, putrid, or decomposed substances or foods that have been prepared, packed, or held under insanitary conditions so that they may become contaminated or may be rendered injurious to health;

• Publicity from private consumer groups or health agencies on the risks from products not manufactured using CGMP regulations, manufacturers assurances, and the voluntary adoption of some or all provisions of the proposed regulations;

• Current or enhanced State and local enforcement activity to bring about a reduction of potential harm from contaminated or poor quality dietary supplements; or

• Litigation or the threat of litigation by consumers who allege harm from consumption of the dietary supplement.

We believe that there are compelling reasons not to rely on these alternatives alone.

If public and private health agencies, consumer groups, competitors, trade organizations or other third parties publicized the risks from products not manufactured using private good manufacturing practices, then consumers would decide for themselves on the risks of contaminated or poor quality products. The weakness of this alternative is that third-party organizations cannot easily discover many of the problems caused by poor manufacturing practices because manufacturers are reluctant to voluntarily share information to third parties about their manufacturing practices.

Actions by manufacturers, such as by voluntarily introducing good manufacturing practices, occur when the expected private economic benefits of the actions exceed the private costs. Voluntary adoption of good manufacturing practices will occur when it is profitable to do so. Many establishments appear to be adopting some publicly available good manufacturing practice models in order to meet the demand for safer and more uniform products. NNFA is implementing a good manufacturing practice certification program. The USP sets standards for strength, purity, disintegration, and dissolution for individual and combination vitamins and minerals. Also, Consumerlab.com is introducing a certification label, CL, to show when ingredients meet their minimum requirements. However, 36 percent of recently surveyed dietary supplement establishments do not follow any good manufacturing practice models for their products (Ref. E2). The breakdown of survey results shows that 48 percent of very small firms, 27 percent of small firms and 11 percent of large firms do not follow a good manufacturing practice model. The survey results also show that 32 percent of vitamins and mineral establishments, 39 percent of amino acid/protein/animal extract establishments, 41 percent of herbal and botanical establishments, and 59 percent of establishments not already classified, do not follow a good manufacturing practice model.

Without industry-wide uniform requirements, some establishments may follow different practices but convey the message that they follow good manufacturing practices. In short, people who want to discriminate between establishments that use good practices and those that do not would not have sufficient information to do so. Another reason for our skepticism about universal voluntary adoption of good manufacturing practices is that good practices appear to be taken for granted by many consumers. Indeed, some consumers already believe that the Federal Government regulates the manufacturing practices of the industry, so firms lack an incentive to provide additional assurance (Ref. E3).

Current or enhanced State and local regulations could bring about a reduction of potential harm from contaminated supplements. This alternative has the advantage that State and local governments can exercise more discretion when responding to local manufacturing conditions or consumer health practices than the Federal Government. Because most of the industry engages in interstate commerce, however, Federal regulations are appropriate. Also, Federal regulations would apply uniformly across the country, whereas State and local regulations might impose different standards on establishments that supply supplements across State and local boundaries.

Litigation or the threat of litigation may help to bring about the goals of the proposed rule. The potential of costly litigation from the harm caused by deficient manufacturing practices creates an incentive for manufacturers to reduce the risks from defective products. However, we do not believe that litigation or the threat of litigation has created the incentives for all manufacturers to implement the manufacturing practices that we believe are necessary to avoid adulterated or misbranded products. As discussed earlier, not all surveyed dietary supplement manufacturers reported that they followed good manufacturing practices. Furthermore, in some cases it is difficult and costly to demonstrate to the courts that the harm to plaintiffs was

actually the result of poor manufacturing practices, making recourse to the courts sometimes impractical.

In the absence of the proposed CGMP regulations, the burden of monitoring manufacturing practices would fall more heavily on consumers, despite the difficulties consumers face in monitoring manufacturers. Moreover, the proposed CGMP regulations are preventative and should ensure that problems are identified and dealt with during manufacturing, packaging, and holding, rather than after someone has consumed an unsafe product and experienced an adverse effect.

b. *Fewer requirements for vitamins and minerals.* FDA could require more controls from establishments that manufacture, package, or hold plant or animal derived dietary ingredients such as amino acids, proteins, herbals, botanicals and other products not classified as vitamin and mineral manufacturers, packagers, or holders. The plant or animal derived dietary ingredients are probably characterized by greater variation in product quality than synthetically derived dietary ingredients. Under this option, the segment of the industry that manufacture, package, or hold products that are the most likely to have difficulty manufacturing or maintaining uniform product quality dietary ingredients would be required to follow the proposed testing and other production and process control requirements. Manufacturers of vitamins and minerals would be required to follow the sanitation, holding, and consumer complaint provisions only, they would not have to adopt manufacturing controls to ensure that products did not contain too much or too little of a vitamin or mineral.

Plant or animal ingredients are likely to experience greater natural variation in product quality than synthetic compounds, so they may require the higher minimum standard of regulation contained in the proposed regulation. The advantage of this option is that fewer establishments will be affected as much; approximately 723 establishments classified as manufacturers, packagers or holders of products other than vitamins and minerals, rather than the 1,566 establishments estimated to be covered by the proposed regulation (*see* table 2 of this document). The compliance costs would therefore be lower. The disadvantage is that vitamin and mineral manufacturers also potentially manufacture products of variable quality, so the expected benefits from more consistent product quality would be reduced. Moreover, if dietary supplements contain too little of a vitamin or mineral consumers may not receive the intended health benefits, and if the dietary supplements contain too much of a vitamin or mineral they may experience illness or injury.

We estimate that the benefits of this option would be approximately proportional to the ratio of recalled products that were classified as vitamins and minerals to all recalled dietary supplements products. Approximately 50 percent of the recalled products were vitamins and minerals so we estimate that this option would generate no more than $109 million in benefits. We assumed that the costs of this option would be proportional to the fraction of establishments that would be required to follow all of the proposed provisions and those that follow the reduced requirements with the total costs estimated for this proposal as shown in table 17 of this document. The estimated mean cost of the proposed regulation is $86 million (see table 19 of this document). The fraction of establishments required to follow all the provisions is .46 (= 723/1566). The fraction of establishments that would have reduced testing is .54 (= 843/1566). Testing is approximately 36 percent of the total costs. We estimate the total costs from this option to be $69 million ($86 million × .46 + $86 million × .54 × (1 − .36)).

c. *More restrictive CGMP regulations than the proposed regulations.* One option is to propose (or finalize) more restrictive rules than the proposed CGMP regulations. Under this option, CGMP regulations could provide consumers with additional safeguards. Several of the largest manufacturers of dietary supplements now voluntarily comply with some of these additional safeguards (Ref. E2). The most significant additional provisions that would be required under this option are product quality testing for each incoming shipment lot of components and dietary ingredients, inprocess testing for contaminates at critical control points and mandatory written procedures for all of the various provisions of the proposed regulation.

The advantage of this option is that the additional requirements provide safeguards that the essential safety and quality provisions are being followed. The disadvantage of this option is that it is more costly than the proposed rule, and we are not aware of any information that would show any additional verifiable health benefits.

d. *HACCP without the other elements of CGMP regulations.* The agency could propose a requirement that manufacturers implement a HACCP (or HACCP like) system for the manufacturing of dietary supplements without the other elements of the proposed CGMP regulations. A critical control point is where production controls can be applied to reduce or eliminate hazards (including biological, chemical, or physical contamination) that may make dietary supplements unsafe.

The advantage of an industry-wide HACCP program is that HACCP does not require manufacturers to follow detailed uniform requirements in order to achieve desirable outcomes. Manufacturers themselves determine for their specific products and processes how they will best eliminate, reduce, or control hazards in the manufacturing of dietary supplements.

We have not designed a hypothetical HACCP system for the dietary supplement industry. For the purpose of generating estimates of costs and benefits, we assumed that a HACCP regulation for a dietary supplement manufacturer would be likely to encompass sanitation prerequisites that are met, writing a HACCP plan, and monitoring critical control points. The benefits and costs of the HACCP plan would be generated by controls for a narrower set of hazards in the manufacturing, packaging, and holding processes than those covered by this proposal, and would not include the other benefits and costs generated by the proposed rule especially the reduced consumer search costs, because uniform product quality would not necessarily be assured. The advantage of HACCP as an option to prevent product contamination is that it does not specify detailed manufacturing requirements. The disadvantage is that in the absence of uniform controls there would not be uniform minimum product quality across the industry and consumers would not derive the same benefits from lower search costs.

e. *Require final product testing only.* FDA could propose that manufacturers test their finished products for identity, purity, quality, strength, and composition but not include any of the other mandatory provisions of the proposed regulation. The advantage of this option is that it would be the least costly option of those considered. Many firms already test some of their finished products, reducing the impact of this option. Approximately 69 percent of manufacturing plants conduct finished product testing and almost 65 percent of all finished batches in the industry are already tested using physical, chemical, microbiological, visual or organoleptic

testing techniques (Ref. E2). The problem with this option is that finished product testing alone cannot ensure product quality for some types of products. Not every finished product currently has a test that confirms identity, purity, quality, strength, or composition, especially for multiingredient products. Tests may not have been developed, or they may not be completely reliable, or they may not be capable of evaluating every type of product defect. Also, potentially lower cost alternatives to finished product testing—such as incoming component lot testing, inprocess testing, or both—might be available and desirable to firms as a means to protect the public. Moreover, finished product testing alone is not sufficient to prevent products with microbiological or chemical contamination from being discovered because it is possible that false negatives might occur, as when there is ''hotspot'' contamination within a batch. Preventative controls must be imposed to achieve that goal. Finally, finished product testing alone also will not facilitate trace backs when defective products are discovered in the marketplace, nor will it facilitate responsible investigations of consumer complaints. The estimated cost of this option is lower than that of the other options, but it does not generate the full range of benefits provided by the proposed rule.

f. *Regulate only high-risk products.* FDA could propose CGMP regulations that would cover only high-risk products. The advantage of this option is that it would impose lower costs than the proposed rule, but (if all risky products could be identified and regulated) generate the same level of benefits. Only those establishments that manufacture high-risk products or have high-risk hazards would incur the costs of adopting CGMP regulations. High-risk might be defined as those products most likely to be contaminated, or suffer other product defects. There are two problems with this option. Adverse event reporting is not mandatory, so significant underreporting is expected. Also, it is possible that the confirmed illnesses and other problems linked to particular dietary supplements may be those most easily traced, rather than those with the highest risk. High levels of identified problems may not be closely correlated with high levels of risk. In other words, problems associated with the known defective products may or may not be correlated with the highest risk. Without more data and risk assessments, it would be difficult to distinguish what risks may be associated with particular dietary supplements. We therefore have no basis upon which to begin a full evaluation of what the high-risk products are or may be.

3. Coverage of the Proposed Rule

The proposed rule would cover establishments that manufacture, package, hold dietary ingredients or dietary supplements. Tables 2, 3, and 4 of this document list the estimated number of covered manufacturers, packagers, dietary ingredient suppliers, holders, and other establishments. Table 2 of this document shows the number of covered establishments by product type and size. A small business, based on the Small Business Administration definition, is any firm with 500 or fewer employees. For purposes of analysis, we defined very small establishments as having fewer than 20 employees. Table 3 of this document shows the number of establishments categorized as manufacturers, ingredient suppliers, repackers or relabelers, holders whose primary business is dietary ingredients or dietary supplements, and other (although not including other holders and distributors). Table 4 of this document shows our estimate of the number of general warehouses and wholesalers that hold dietary supplements.

TABLE 2.—COVERED ESTABLISHMENTS BY PRODUCT TYPE AND SIZE FROM DIETARY SUPPLEMENT ENHANCED ESTABLISHMENT DATABASE (DS–EED)

| Product type | Very small | % | Small | % | Large | % | Unknown | % | Total |
|---|---|---|---|---|---|---|---|---|---|
| Vitamins and Minerals | 252 | 29.8 | 223 | 26.5 | 78 | 9.2 | 290 | 34.5 | 843 |
| Amino Acids, Proteins | 21 | 31.0 | 16 | 23.0 | 6 | 6.9 | 27 | 39.1 | 69 |
| Herbals and botanicals | 148 | 42.6 | 46 | 13.2 | 5 | 1.1 | 150 | 43.1 | 348 |
| Supplements not already classified | 93 | 30.4 | 66 | 21.6 | 20 | 6.5 | 127 | 41.6 | 306 |
| Total | 514 | 32.8 | 351 | 22.4 | 106 | 6.8 | 594 | 38.0 | 1,566 |

TABLE 3.—COVERED ESTABLISHMENTS BY TYPE OF OPERATION FROM DS–EED

| Establishment type | Number of establishments | Percent of establishments |
|---|---|---|
| Manufacturer | 1,228 | 78.4 |
| Dietary ingredient supplier | 106 | 6.7 |
| Repacker; relabeler | 26 | 1.7 |
| Holder | 114 | 7.3 |
| Establishments not already classified | 92 | 5.9 |
| Total | 1,566 | 100.0 |

TABLE 4.—COVERED ESTABLISHMENTS THAT HOLD DIETARY SUPPLEMENTS

| Type of holders | Source and SIC code | Number of establishments |
|---|---|---|
| Grocery Wholesalers or Drug Wholesalers | Dunn and Bradstreet: 5122, 5141 | 25,527 |
| Food or Drug Warehouse | Dunn and Bradstreet: N/A | 738 |
| Miscellaneous Food or Drug Warehouse | Dunn and Bradstreet: 4225, 4226, 5912, 5499, 5411, 5122, 5141, 5149, 5399, 5311, and 5331. | 238 |

TABLE 4.—COVERED ESTABLISHMENTS THAT HOLD DIETARY SUPPLEMENTS—Continued

| Type of holders | Source and SIC code | Number of establishments |
|---|---|---|
| Dietary Supplement | DS–EED | 114 |
| Total | | 26,617 |

We consulted several sources to estimate the number of establishments reported in tables 2, 3, and 4 of this document. The number shown in tables 2 and 3 of this document, 1,566, is the estimated number of establishments in the DS–EED that manufacture, repackage, supply dietary ingredients, or hold dietary supplement products in the United States. RTI developed the DS–EED using FDA's Official Establishment Inventory (OEI) and supplemented that source with information from trade organizations, trade shows, and electronic databases (Refs. E1 and E2).

The number of establishments in the DS–EED that hold dietary supplements is not the total number of holders covered by the proposed regulation. The holding establishments in the DS–EED identified holding dietary supplements as their primary business. To estimate the total number of establishments that could hold dietary ingredients or dietary supplements but do not consider dietary supplements as their primary business, we performed three searches of firms that are listed with Dun and Bradstreet's Dialog database. We first looked for a count of firms that had standard industrial classification (SIC) codes for wholesalers of groceries or drugs. Next we looked for a count of firms that met the description of warehouses of groceries or drugs (no SIC codes were used). Finally, we looked for a count of any firms that had both warehouse SIC codes and miscellaneous drug stores, food stores, sundries, and general merchandise (SIC 4225, 4226, 5912, 5499, 5411, 5122, 5141, 5149, 5399, 5311, and 5331). The results are shown in table 4 of this document. We concluded that the total number of establishments in this category that could hold dietary ingredients or dietary supplements and would be covered by the regulation was approximately the sum of the numbers counted in the three searches, or 26,617.

The number of establishments that hold dietary ingredients or dietary supplements includes retailers that sell dietary supplements to consumers, and transporters of dietary ingredients and dietary supplements. We made no effort to determine the number of such holders, because the proposed requirements do not apply to retailers and transporters. We believe that retailers and transporters may voluntarily adopt provisions related to the holding of these products and thus there may be changes in the marketplace with accompanying costs and benefits. However, we expect that the only retailers and transporters that will voluntarily adopt the proposed requirements are those that expect the private benefits of adoption will exceed the private costs.

4. Baseline Practices

a. *Consumer baseline practices.* Baseline consumer and manufacturer practices, governed by current market forces and existing government regulations, give rise to the current risks associated with the manufacturing of dietary supplements. When determining baseline manufacturing practices, it is necessary to estimate both the practices that are used now, as well as the likely changes in manufacturing practices that will occur even in the absence of new regulations. The risks to consumers from these products can be associated with a combination of consumption habits, the contamination of the products, or both. Contamination may be caused by current manufacturing practices. Consumption is influenced by the price and quality of dietary supplements, set by the interaction of market participants. Finally, changes in practices of either consumers or manufacturers caused by new regulatory requirements will give rise to changes in risks, as estimated by changes in costs and benefits.

The consumption of dietary supplements has grown in recent years. Consumers report that they are using a wider range of product types, and that they are using dietary supplements for more reasons than they were in the past.

Table 5 of this document illustrates the rapid sales growth of the dietary supplement industry from 1994 to 2000. Panel A of table 5 of this document shows annual sales of three general categories of dietary supplements, a measure of the market size of the supplement industry. Annual increases in sales of herbals and botanicals were the greatest, averaging 18 percent per year, while annual increases in sales of supplements that were neither vitamins and minerals nor herbals and botanicals increased less, averaging 11 percent per year. The lowest annual sales increases were for vitamins and minerals, averaging 8 percent per year. For all dietary supplements combined, sales increased an average of 12 percent a year since 1994 (not shown on the table).

While the sales growth shown in table 5 of this document, Panel A, is impressive, only part of this apparent growth represents increased use. Population growth and rising prices also contributed to the apparent growth. The real (growth inflation-adjusted) increase in dietary supplement prices is estimated by subtracting the inflation rate from the rate of price increases of dietary supplements (Ref. E4). As shown in table 5 of this document, Panel B, between 1995 and 1997 the real price of vitamins and minerals and supplements other than vitamins and minerals all increased. Rising real price indicates that demand is growing rapidly.

Table 5 of this document, Panel C, shows estimated annual increases in per capita consumption of dietary supplements.[1] As shown in table 5 of this document, Panel C, the estimated per capita consumption of the different categories of dietary supplements has increased since 1994.

For the consumption estimates in table 5 of this document, we averaged dietary supplement use over the entire U.S. population, 275 million. In table 6 of this document, we included estimated average supplement use for the population of supplement users, 160 million (Ref. E13). The three panels in table 6 of this document show the annual consumption per supplement user and the annual change in consumption per supplement user for

[1] An index measuring per capita consumption of dietary supplements can be derived using the following equation: $PCC_t = [1{,}000 \times Sales_t]/[POP \times P_t]$, where, t = year index; $PCC_t$ = per capita consumption (# of unit sales); Sales = millions of dollars of sales; $POP_t$ = thousands of U.S. residents; $P_t$ = average price of supplement. In the formula, we measure consumption as the number of dietary supplement units (bottles, packages, etc.) sold per U.S. resident for a given year.

vitamins and minerals, herbals and botanicals, and supplements other than vitamins and minerals and herbals and botanicals. Table 6 of this document also shows that during this period the proportion of consumers using supplements increased faster than the average consumption for the total population. The surprising implication of this result is that consumption per user has apparently declined since 1994.

One limitation of the estimates in table 6 of this document is that prevalence of supplement use is based on the proportion of U.S. adults consuming supplements, while the per capita consumption figures are based on the entire U.S. population. Nonetheless, we do not have any reason to believe that the estimated trend in consumption per user is biased. This trend, expressed as the percentage change in consumption per user, is negative for all segments of the dietary supplement industry since 1994. The large and rising number of consumers accounts for the growing size of the dietary supplement industry.

TABLE 5.—GROWTH IN MARKET SIZE AND PER CAPITA CONSUMPTION OF DIETARY SUPPLEMENTS, 1994–2000

| | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
|---|---|---|---|---|---|---|---|
| **Panel A—Nominal Market (Millions of Current Dollars)** | | | | | | | |
| Vitamins | 3,960 | 4,220 | 4,780 | 5,190 | 5,550 | 5,940 | 6,360 |
| Growth rate (percent) | ..... | 6.57 | 13.27 | 8.58 | 6.94 | 7.03 | 7.07 |
| Minerals | 700 | 800 | 900 | 1,070 | 1,160 | 1,250 | 1,350 |
| Growth rate (percent) | ..... | 14.0 | 13.0 | 19.0 | 8.0 | 8.0 | 8.0 |
| Herbals and Botanicals | 2,070 | 2,530 | 2,990 | 3,530 | 4,170 | 4,840 | 5,520 |
| Growth rate (percent) | ..... | 22.22 | 18.18 | 18.06 | 18.13 | 16.07 | 14.05 |
| Supplements other than vitamins/minerals and botanicals | 2,070 | 2,290 | 2,620 | 2,890 | 3,180 | 3,490 | 3,840 |
| Growth rate (percent) | ..... | 10.63 | 14.41 | 10.31 | 10.03 | 9.75 | 10.03 |
| Total | 8,080 | 9,840 | 11,290 | 12,680 | 14,060 | 15,520 | 17,070 |
| Growth rate (percent) | ..... | 12.0 | 15.0 | 12.0 | 11.0 | 10.0 | 10.0 |
| **Panel B—Prices** | | | | | | | |
| Consumer price index-units (percent) | 148.5 | 152.5 | 157.0 | 160.5 | 163.2 | 166.7 | ..... |
| Inflation rate (percent) | 2.56 | 2.76 | 2.957 | 2.23 | 1.68 | 2.14 | 2.39 |
| Vitamins and minerals | ..... | ..... | ..... | ..... | ..... | ..... | ..... |
| Average nominal price (IRI) | $6.20 | $6.50 | $6.87 | $7.34 | $7.54 | $7.78 | $8.05 |
| Nominal price increase (percent) | 2.69 | 4.84 | 5.69 | 6.84 | 2.72 | 3.18 | 3.43 |
| Real price increase (percent) | 5.25 | 2.08 | 2.74 | 4.61 | 1.04 | 1.04 | 1.04 |
| Supplements other than vitamins and minerals: | | | | | | | |
| Average nominal price | $6.20 | $6.50 | $6.87 | $7.34 | $7.70 | $8.11 | $8.56 |
| Nominal price increase (percent) | 5.80 | 4.84 | 5.69 | 6.84 | 4.85 | 5.31 | 5.56 |
| Real price increase (percent) | 3.24 | 2.08 | 2.74 | 4.61 | 3.17 | 3.17 | 3.17 |
| **Panel C—Per Capita Consumption (Number of Units Sold Per U.S. Resident)** | | | | | | | |
| Vitamin/mineral sales | 2.45 | 2.47 | 2.62 | 2.64 | 2.72 | 2.80 | 2.87 |
| Growth (percent) | ..... | 0.69 | 6.19 | 0.66 | 3.12 | 2.74 | 2.55 |
| Herbals sales | 1.28 | 1.48 | 1.64 | 1.80 | 2.00 | 2.19 | 2.34 |
| Growth (percent) | ..... | 15.48 | 10.79 | 9.45 | 11.60 | 9.17 | 7.03 |
| Supplements other than vitamins and minerals and herbals sales | 1.28 | 1.34 | 1.44 | 1.47 | 1.53 | 1.58 | 1.63 |
| Growth (percent) | ..... | 4.53 | 7.26 | 2.26 | 3.95 | 3.23 | 3.25 |

TABLE 6.—COMPARISON OF CONSUMPTION PER PERSON WITH CONSUMPTION PER USER: EVIDENCE THAT THE DIETARY SUPPLEMENT MARKET IS BECOMING BROADER NOT DEEPER

| Average Growth | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 1994–2000 |
|---|---|---|---|---|---|---|---|
| **A. Vitamins and Minerals** | | | | | | | |
| Per capita consumption (units per U.S. resident) | 2.45 | 2.47 | 2.62 | 2.64 | 2.72 | 2.80 | ..... |
| % Growth | ..... | 0.69 | 6.19 | 0.66 | 3.12 | 2.74% | 2.68% |
| Consumption prevalence (percent) | ..... | 47.70 | 54.0 | 61.0 | 70.0 | 79.0 | ..... |
| Reference | ..... | Ref. E6 | Ref. E6 | Ref. E6 | Ref. E6 | Ref. E7 | ..... |
| % Growth | ..... | ..... | 13.44 | 13.44 | 13.44 | 13.44 | 13.44 |
| Consumption per user (units) | ..... | 5.18 | 4.85 | 4.30 | 3.91 | 3.54 | ..... |
| % Growth | ..... | ..... | −6.39 | −11.27 | −9.10 | −9.43 | −9.05 |
| | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 1994–1999 |
| **B. Herbals and Botanicals** | | | | | | | |
| Per capita consumption (units per U.S. resident) | 1.28 | 1.48 | 1.64 | 1.80 | 2.00 | 2.19 | ..... |

TABLE 6.—COMPARISON OF CONSUMPTION PER PERSON WITH CONSUMPTION PER USER: EVIDENCE THAT THE DIETARY SUPPLEMENT MARKET IS BECOMING BROADER NOT DEEPER—Continued

| Average Growth | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 1994–2000 |
|---|---|---|---|---|---|---|---|
| % Growth | ..... | 15.48 | 10.79 | 9.45 | 11.60 | 9.17 | 11.30 |
| Consumption prevalence (percent) | 8.20 | 12.10 | 12.10 | 12.10 | 28 | 49 | ..... |
| Reference | Ref. E8 | Ref. E8 | Ref. E8 | Ref. E9 | Ref. E10 | Ref. E7 | ..... |
| % Growth | ..... | 47.56 | 0.00 | 0.00 | 131.40 | 75.00 | 50.79 |
| Consumption per user (units) | 15.64 | 12.24 | 13.56 | 14.84 | 7.16 | 4.47 | ..... |
| % Growth | ..... | −21.74 | 10.79 | 9.45 | −51.77 | −37.62 | −18.18% |
| **C. Supplements Other than Vitamins and Minerals and Herbals and Botanicals** | | | | | | | |
| Per capita consumption (units per U.S. resident) | 1.28 | 1.34 | 1.44 | 1.47 | 1.53 | 1.58 | ..... |
| % Growth | ..... | 4.53 | 7.26 | 2.26 | 3.95 | 3.23 | 4.24 |
| Consumption prevalence (percent) | 5.1 | 8.8 | 11.2 | 14.2 | 18.1 | 23.0 | ..... |
| Reference | Ref. E8 | Ref. E8 | Ref. E8 | Ref. E8 | Ref. E8 | Ref. E7 | ..... |
| % Growth | ..... | 72.55 | 27.15 | 27.15 | 27.15 | 27.14 | 36.23 |
| Consumption per user (units) | 25.15 | 15.24 | 12.85 | 10.34 | 8.45 | 6.86 | ..... |
| % Growth | ..... | −39.42 | −15.64 | −19.58 | −18.25 | −18.81 | −22.34 |

b. *Manufacturer's baseline practices.* FDA 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 sample was stratified by manufacturer's product type and the size of firm in the industry. Stratification helps ensure that estimates of the subpopulations are more precise. Establishments that were stratified by manufacturer's product type were classified as primarily: (1) Vitamins and minerals; (2) amino acids, proteins, or animal extracts; (3) herbals and botanicals; or (4) all other product types not already classified. The product type strata were further stratified by four size categories: (1) Very small, (2) small, (3) large, and (4) unknown. This categorization generated 16 sampling strata.

The contractor, RTI, sent each of the 966 firms in the sample a lead letter on FDA letterhead and a one-page brochure to explain the purpose of the survey, the value of the establishment's participation, and the agency's confidentiality procedures. Following the mailing, RTI placed telephone calls to each establishment to screen for eligibility and to recruit eligible establishments for the mail survey. To be eligible for the survey, establishments had to currently manufacture, repackage, supply dietary ingredients, hold, import or export dietary supplements for human consumption. Almost 50 percent of the establishments sampled were not eligible for the survey because they were no longer in operation at the listed address or did not handle any dietary supplements or ingredients for human consumption.

To achieve the highest possible response rate, RTI operated a toll-free help line and attempted to contact each establishment up to eight times before assigning a disposition of nonresponse. RTI also attempted up to two refusals conversions, which are attempts to persuade firms that declined to answer the survey to respond. The survey was conducted over a 10-week period, November 29, 1999, to February 4, 2000. There were a total of 238 completed surveys, resulting in a final disposition of: (1) An overall eligibility rate of close to 50 percent, and (2) a response rate of 50 percent.

Determining baseline practices is necessary in order to determine the new activities that are likely to take place as a result of implementation of this proposed rule. Each of the new activities potentially brought about by the proposed rule has both a marginal (or incremental) cost and a marginal (or incremental) benefit. These incremental costs and benefits of likely new activities form the basis of our economic analysis of the proposed rule.

The survey asked establishments a series of questions about existing practices; we used the responses to estimate how many establishments in the industry already operated in accordance with the requirements of the proposed regulation. One key assumption in this analysis is that no firms are expected to stop CGMPs and no firms are expected to start good manufacturing practices in the absence of this rule. The universe for the survey includes the establishments discussed in section VII.B.3 of this document. If firms start good manufacturing practices in the absence of this rule, both the costs and benefits of the rule would be less than we estimate. If firms were to stop in the absence of the rule, both the costs and benefits would be more than we estimate. We lack information about the trend in the industry, so we assumed that the survey reflects both the current and future practices in the industry. We request comment or information about the industry trend in adopting good manufacturing practices.

i. *Stratification.* The survey was stratified by product type and establishment size. Stratification ensures that samples are representative of the industry population.[2] The subdivisions of the population of interest here were establishment size (by the number of employees) and product type, because these characteristics are likely to influence whether an establishment already has adopted the practices that would be required by the regulation. The DS–EED includes nine product types: (1) Vitamins and minerals; (2) herbals and botanicals; (3) herbal and botanical extracts; (4) amino acids; (5) proteins; (6) animal extracts; (7) tea like products; (8) concentrates, metabolites, or constituents; and (9) supplements not already classified (all other supplements). Establishments may produce more than one product type; establishments with multiple product types were, however, only classified in one category. For stratification and reporting purposes, we defined the

[2] Stratification is a subdivision of the population of establishments in the dietary supplement industry by a unique characteristic such as product type or number of employees.

following four mutually exclusive categories of dietary supplements:

1. Vitamins and minerals (includes establishments that may also manufacture, package, or hold herbals and botanicals, amino acids, proteins, or animal extracts but predominately manufacture vitamins and minerals);
2. Amino acids, proteins, and animal extracts (includes establishments that also manufacture, package or hold herbals and botanicals, including extracts; excludes establishments already classified as vitamins and minerals);
3. Herbals and botanicals, including extracts (excludes establishments already classified as ''vitamins and minerals'' or ''amino acids, proteins, or animal extracts''); and
4. Supplements not already classified (all other product types).

We further stratified each of the four product categories into four size categories, very small, small, large, and unknown—resulting in 16 sampling strata. We classified each establishment into one mutually exclusive industry category (manufacturer, dietary ingredient supplier, repacker/relabeler, holder, or establishment not already classified). Establishments that manufacture supplements and also supply, repack, or hold dietary supplements or ingredients were classified as manufacturers.

ii. Size stratification. 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 500 or fewer employees, they are classified as small. Because the DS–EED data on size are only for specific establishments and not parent firms, we had to obtain parent company information on employment or revenue to correctly classify each establishment as part of a small or large company. To obtain parent company data for establishments in the survey universe, we sent *Info*USA [3] the DS–EED data records (N = 2,004) and requested the name, address, primary SIC, employment size (in ranges), and revenue (in ranges) of parent company firms with establishments in the survey universe. *Info*USA matched 1,219 of the 2,004 records in the DS–EED to their U.S. database of 10.3 million businesses. Of the 1,219 matched records, 31 records were found to be duplicates of another record and were removed, leaving 1,188 matched records and 1,566 total records in the sampling frame. The nonmatched records did not match because: (1) They were recently established businesses, (2) they were out of business, or (3) they had recently changed their names or addresses. Because data on revenue or employment size were not available for the nonmatched records, we created an ''unknown'' stratum for these establishments. The survey of practices collected information on employment that allowed us to classify some of these establishments by size for the analysis.

Of the 1,188 matched records, 180 were linked to parents. The parent company data for these 180 establishments were merged with the survey universe. The remaining 1,008 records did not link to an ultimate parent company. For these records, the establishment and parent company were the same entity, so we used establishment level data to classify size. We classified each of the establishments in the survey universe as part of very small, small, or large businesses based on the employment size or annual revenues of each establishment's parent company. If an establishment or its parent company had 500 or fewer employees or sales less than $20 million (if data on employment were not available), then the establishment was classified as small. An establishment was classified as very small if the number of employees was less than 20.

iii. *Survey response.* Table 7 of this document presents the number of establishments surveyed, stratified by the four product types and by size. Although the sample allocation was designed to yield 400 completed surveys, we received only 238 completed mail surveys. The number of respondents was fewer than expected because the number of establishments that were ineligible was greater than we expected and because some establishments did not respond to the survey after agreeing to participate. Ineligible establishments are those that no longer produce dietary supplements because they have gone out of business or changed product lines, or they have moved and could not be located. Despite receiving fewer responses than planned, the confidence level for the final results allowed us to make meaningful inferences regarding the industry. For example, 65 percent of the establishments surveyed responded that they followed published good manufacturing practice models; the 95 percent confidence interval was 56 to 72 percent. By size category, 52 percent of very small, 73 percent of small, and 89 percent of large establishments responded that they followed published good manufacturing practice models (Ref. E2). Although we do not suggest that these percentages are precise, they do tell a plausible story of the current use of good manufacturing practice models in the supplement industry: The use of good manufacturing practice models appears to be widespread but far from universal, with use more likely the larger the establishment.

TABLE 7.—NUMBER OF COMPLETED SURVEYS BY SAMPLING STRATA

| Product type | Size | | | | |
|---|---|---|---|---|---|
| | Very small | Small | Large | 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 |

The mean survey results reflect the degree of uncertainty associated with each practice. The use of a survey for this economic analysis often required the use of the survey answers from more than one question to assess the impact

[3] *Info*USA is a publicly held company that creates proprietary business databases. Their database includes such information as: Company name, address, phone number, fax number, estimated sales, volume, number of employees, type of business (SIC code or yellow page heading), key contact names, and titles.

of each proposed provision. For example, answers to questions about testing herbals might have been combined with questions about whether the firms manufactured herbals. Some highlights of the survey are:

- Plant characteristics: Manufacturers account for 62 percent of the total firms and 36 percent of manufacturers produce vitamins and minerals as their primary product.
- Use of published good manufacturing practice model: 65 percent of all firms follow some type of good manufacturing practice model, primarily food good manufacturing practices; 28 percent follow the NNFA good manufacturing practices and 31 percent follow FDA's drug good manufacturing practice requirements.
- Personnel: 67 percent of all establishments maintain records of personnel education, training, or experience.
- Quality control: 85 percent of all establishments have a unit or person responsible for quality control. Almost 80 percent of all manufacturers conduct at least some type of identity tests on incoming components and dietary ingredients and 96 percent of these firms also conduct some type of contamination test; 63 percent conduct some type of potency test. Nearly 70 percent conduct tests on inprocess materials or finished products. Of these firms, 97 percent conduct identity tests, 94 percent conduct contamination tests and 72 percent conduct potency tests. Asked whether firms hold reserve samples of each finished batch, 75 percent answered yes. Of the plants that have production processes, 70 percent use production and process controls that identify the points, steps, or stages in the manufacturing process to prevent adulteration. Almost 68 percent of all incoming ingredient or component lots are tested now and almost 70 percent of inprocess or finished product batches are tested in some manner.
- Warehousing: 70 percent of warehouses have temperature controls and 22 percent have humidity controls.
- Consumer complaints: Only 19 percent report incidents to FDA.

5. Baseline Risk

The current number of illnesses caused by poor manufacturing practices requires data linking illnesses directly to poor practices. Without direct evidence on the number of illnesses caused by poor manufacturing practices, we had to use an indirect approach. There are two indirect ways to estimate the number of illnesses caused by defective products:

- We could take the number of reported cases and multiply by a factor to account for underreporting.
- We could take the number of defective products and multiply by the probability of illness for the given defect.

In an ideal analysis, we would estimate the baseline both ways and then compare them. For the analysis of illnesses from poor manufacturing practices, however, we did not have sufficient data to perform either type of baseline estimate.

We looked at many sources for information, including medical and other literature on adverse events, information from poison control centers, reports to the agency, popular newspaper and magazine articles, and surveys of users. The literature review was conducted using Medline, Healthstar, Aidsline, Cancerlit, and OldMedline (Ref. E12). We found evidence of many adverse events associated with dietary supplements. For example, one recent survey found that 12 percent of consumers (about 11.9 million) who have used an herbal remedy claim to have suffered from side effects or other adverse reactions (Ref. E13). The American Association of Poison Control Centers received 6,914 reports on dietary supplements in 1998 (Ref. E14). In a recent survey, 46 percent of respondents answered that people get sick from dietary supplements ''often'' or ''sometimes'' (Ref. E3). In addition, the agency has received many voluntary reports of illnesses caused by dietary supplements (Ref. E15). The vast majority of the illnesses described in the sources we consulted, however, are reported as associated with the ingredients used in the products themselves, not with poor manufacturing processes. We have no direct evidence on what fraction of illnesses can be attributed to manufacturing processes. The anecdotal evidence implies that many illnesses could have been caused by poor manufacturing processes, but with a few exceptions, no evidence explicitly links illnesses to these manufacturing processes.

The agency's recall records are more useful than the reports on illnesses, because the class 1 and class 2 recalls all involve defective products that could have caused illness if ingested. The major public health events that have been linked to poor manufacturing processes show up in the list of dietary supplements recalled. 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 manufacturing mistakes. We have recall data that show that manufacturing mistakes exist, so we can construct a possible link between manufacturing mistakes and potential illnesses or injuries. The number of illnesses associated with a recall is both variable and uncertain, and could be anything from zero to quite large. We concluded that one illness would not be an implausibly high average for a recall, so we assumed that a recalled product could be a proxy for a single reported illness associated with a defective product. We ask for comments on this assumption.

Because there are no well established systems for the notification of adverse health events related to dietary supplements, and some significant barriers to reporting, we assume that unreported illnesses caused by poor manufacturing practices are substantially greater than reported illnesses. We relied on Ref. E16 to estimate a more precise relationship between reported and unreported rates. Based on empirical data for drug and vaccine reporting rates among other studies, the author of Ref. E16 determined that for dietary supplements, reported illnesses represent at best approximately 1 percent of total illnesses (Ref. E16). A similar multiplier of 100 linking known cases of foodborne illness to total incidence is often used. We assume that reporting adverse health events due to poorly manufactured dietary supplements would occur at the same proportion as adverse health events caused for other reasons by dietary supplements. We show the sensitivity of benefits to the choice of multiplier below, in the uncertainty and sensitivity analysis of our results.

The outbreak of eosinophilia-myalgia syndrome (EMS) resulting from contaminated L–Tryptophan resulted in the recall of the contaminated products. In part based on this example, we assume that product recalls can indicate when there are adverse health events. We also assume that the reported class 1 and class 2 recalls that have occurred over the last 10 years represent the number and type of recalls that will occur in the future but for the implementation of this regulation. From 1990 through 1999, the agency received reports on an annual average of 13 class 1 and class 2 recalls of dietary supplements. If each recall is a proxy for a reported illness, then the total number of unreported illnesses per year is approximately 1,300. Obviously, to the extent that products are successfully recalled, illnesses will be avoided. Our assumption is that the recall occurs

because at best one person on average has been made ill. We recognize that our procedure generated highly uncertain estimates of the number of illnesses. The use of recalls to estimate reported and unreported illnesses probably generated a distribution of illnesses below the ''true'' distribution, because many illnesses occur that are not linked to recalls and are never reported. We were not able to determine even the approximate size of the underestimation from this procedure.

We estimated the monetary value of the health benefits from CGMP regulations by multiplying the number of illnesses prevented by the health costs associated with an illness. The health benefits associated with preventing an illness come from: (1) Preventing the loss of productivity, (2) the reduction in pain and suffering, and (3) the reduction in expenditures on medical treatment. We measured lost 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 used direct measures of medical costs, such as payments to physicians and hospitals.[4]

Table 8 of this document contains summaries of our measures of the health effects potentially caused by known instances of defective products associated with poor manufacturing processes. 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[5]). These losses per day can be interpreted as the difference between a day of normal health, where normal is defined as the population's health not affected by these products, 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 value of a statistical life day and adding the direct medical costs.

TABLE 8.—SUMMARY OF HEALTH EFFECTS BASED ON POTENTIAL ILLNESS ASSOCIATED WITH RECALLS BETWEEN 1990 AND 1999

| Problem | Class of recall | Number of recalls | Outcomes | Frequency of illness (percent) | Quality adjusted life day | Duration of illness (days) | Medical cost ($) per event | Health cost ($) per event |
|---|---|---|---|---|---|---|---|---|
| Hypervitaminosis A | 1 | 2 | ..... | 100 | 0.472 | 3 | 84 | 936 |
| Salmonella | 1 | 4 | Mild | 93.8 | 0.473 | 2 | 0 | 534 |
| | | | Moderate | 5 | 0.473 | 5 | 800 | 2,223 |
| | | | Severe | 1.2 | 0.563 | 17 | 9,100 | 14,859 |
| | | | Reactive arthritis (short term). | 2 | 0.42 | 25 | 100 | 6,438 |
| | | | Reactive arthritis (long term). | 1 | 0.42 | 5,223 | 400 | 1,320,252 |
| | 2 | 4 | Death | 0.04 | ..... | ..... | 9,100 | 5,009,100 |
| Klebsiella pneumonia | 1 | 1 | Severe | 85 | ..... | ..... | 6,235 | 10,650 |
| | | | Death | 15 | ..... | ..... | 6,235 | 5,006,325 |
| Selenium poisoning | 1 | 1 | Low doses | 50 | 0.482 | 3 | 84 | 954 |
| | | | Severe | 35 | 0.482 | 3 | 2,578 | 4,448 |
| | | | Death | 15 | ..... | ..... | 2,578 | 5,002,578 |
| Stannous fluoride | 1 | 1 | Acute | 100 | 0.473 | 3 | 84 | 938 |
| | 2 | 1 | ..... | ..... | 0.473 | 3 | 84 | 938 |
| Eosinophilia-myalgia syndrome. | 1 | 7 | Mild | 47 | 0.482 | 5,223 | 1,176 | 1,515,863 |
| | | | Moderate | 50 | 0.482 | 60 | 84 | 17,484 |
| | 2 | 41 | Severe | 10 | ..... | ..... | 14,964 | 27,394 |
| Glass fragments | 2 | 1 | Dental injury, simple | 50 | 0.231 | 1 | 139 | ..... |
| | | | Dental injury, complicated. | 12 | ..... | ..... | 3,741 | ..... |
| | | | Oral emergency | 12 | ..... | ..... | 3,741 | 6,428 |
| | | | Tracheo-esophageal obstruction. | 25 | ..... | ..... | ..... | 290 |
| | | | Esophageal perforation. | 1 | ..... | ..... | 14,964 | 23,343 |
| Hypervitaminosis D | 2 | 1 | ..... | 100 | 0.473 | 3 | 168 | 1,022 |
| Pyridoxine (vitamin B6). | 2 | 2 | ..... | 100 | 0.482 | 30 | 168 | 8,868 |
| Super-potent zinc | 2 | 1 | Mild | 50 | ..... | ..... | ..... | 285 |
| | | | Moderate | 40 | ..... | ..... | ..... | 596 |
| | | | Severe | 10 | ..... | ..... | 1,247 | 3,347 |
| Niacin | 2 | 1 | ..... | 100 | ..... | ..... | 84 | 4,258 |
| Yellow #5 (undeclared). | 2 | 5 | Mild allergic reaction | 90 | 0.44 | 2 | 0 | 529 |
| | | | Severe allergic reaction. | 10 | ..... | ..... | 2,494 | 3,346 |

[4] The cost of a hospital day is from the Health Care Financing Agency's Indicator Tables. It is the amount per patient day in 1997, adjusted to 1999 dollars. *See* Ref. E17.

[5] Functional Status Code is a measure of lost mobility (MOB), physical activity (PAC) and social activity (SOC). Lost MOB might mean an inability to drive a car. Lost PAC might mean walking with physical limitations. Lost SOC might mean self-care is not possible. Symptom-problem health utility index is a weighted measure of the cost of each symptom. For example, a sick or upset stomach has a utility weight of .290.

TABLE 8.—SUMMARY OF HEALTH EFFECTS BASED ON POTENTIAL ILLNESS ASSOCIATED WITH RECALLS BETWEEN 1990 AND 1999—Continued

| Problem | Class of recall | Number of recalls | Outcomes | Frequency of illness (percent) | Quality adjusted life day | Duration of illness (days) | Medical cost ($) per event | Health cost ($) per event |
|---|---|---|---|---|---|---|---|---|
| | | | Contact dermatitis | 50 | | | 84 | 1,205 |
| Yellow #6, red #40, blue #2 (undeclared). | 2 | 1 | Abdominal cramps | 10 | 0.473 | 3 | 84 | 938 |
| | | | Contact dermatitis | 90 | | | 84 | 1,205 |
| Copper salts | 2 | 1 | | 100 | 0.473 | 1 | 84 | 369 |
| Digitalis | 1 | 33 | Mild | 94.9 | 0.473 | 3 | 84 | 938 |
| | | | Severe (heart block) | 5 | | | 1,247 | 455,883 |
| | | | Death | 0.1 | | | | 5,000,000 |
| Ephedra (undeclared) | 1 | 1 | Cardiovascular | 14 | | | 1,415 | 3,530 |
| | | | CVS w/chronic | 2 | | | 2,591 | 457,227 |
| | | | Nervous system | 14 | 0.47 | 2 | 1,331 | 1,900 |
| | | | NS w/chronic | 2 | | | 2,507 | 455,597 |
| | | | Liver impairment | 4 | | | 168 | 4,342 |
| | | | Exfoliative dermatitis | 7 | | | 84 | 1,206 |
| | | | Other | 54 | 0.29 | 1 | 0 | 174 |
| | | | Death | 3 | | | 2,507 | 5,002,507 |
| Lactose (undeclared) intolerance. | 2 | 1 | Mild | 100 | 0.48 | 1 | 0 | 290 |
| Iron poisoning | 2 | 1 | Mild | 100 | 0.48 | 1 | 84 | 374 |
| Sulfites (undeclared) | 1 | 1 | Mild allergic reaction | 100 | 0.44 | 2 | 0 | 529 |

We used the transformed value of statistical life to estimate the value of QALD. For the most likely value of a statistical life day, we used $630. We derived this value from a widely-used estimate of the value of a statistical life: $5 million. The $5 million estimate is based on calculations matching labor market risks with wages for risky jobs. Workers in risky jobs tend to receive increased wages to compensate them for (usually) small increases in the probability of death. The implicit value of a statistical life is the increased wage divided by the increased probability of death. The advantage of valuing statistical lives with this method is that it reflects the observed willingness of workers, and by inference, of the whole population of adults, to accept small risks to their lives in a real world risk-dollar tradeoff.

We turn the estimated value of a statistical life into a value of a statistical life day by first assuming that the workers have a remaining life expectancy of 36 years (Ref. E18). Using a 3 percent social rate of time preference, the present value of 36 years is 21.83 years. The social rate of time preference is the average long-term real rate of interest, with no premiums for risk and other factors that affect interest rates. Most analysts use the average real rate on long-term treasury bonds (3 to 5 percent in recent years) to represent the social rate of time preference. The discounted expected days lost for a statistical death is 21.83 x 365 = 7,968. Therefore, the value of a statistical day is $5 million/7,968, which is approximately $630. We use this value to estimate the public health benefits from preventing illness.

In addition to lost productivity and pain and suffering, illness caused by supplement contamination leads to direct medical costs. Direct medical costs include the cost of medicine, hospitalization, and visits to physicians and other professionals. We included all estimated medical costs, not just out-of-pocket expenses. These full medical costs often are missed because most medical care is covered by health insurance that separates the bearer of the medical cost (society) from the bearer of the utility losses (the ill person).

The total costs of illnesses caused by the contamination of dietary supplements from poor manufacturing practices would be the costs per illness (classified by severity) multiplied by the number of illnesses (classified by severity). For chronic illnesses, the utility losses and medical costs stretch indefinitely into the future. We used a real discount rate of 7 percent to calculate the present value of chronic medical expenditures and utility losses. OMB suggests using a real discount rate of 7 percent to analyze the costs and benefits of regulations. This rate approximates the marginal rate of return on an average investment in the private sector in recent years. We used a different discount rate for the social rate of time preference (3 percent) and the discount rate of future medical costs (7 percent). Medical costs, like all expenditures, reflect the foregone benefits from alternative investments. The pure social rate of time preference can differ from the return on private investments.

6. Benefits and Costs

Changes in current practices by manufacturers, or consumers, or both, cause incremental (marginal) benefits and costs. There are several possible reactions manufacturers might have to the proposed regulatory requirements:

- Stop producing dietary supplements and possibly go out of business.
- Move production to a foreign country where compliance with these regulations is more difficult to enforce.
- Comply with part or all of the proposed regulation. Consumers will likely be confronted with higher priced dietary supplements but also products that are, on average, more uniform and higher quality. To the extent that the latter is unknown to consumers, they will probably reduce consumption of dietary supplements, perhaps in some cases substituting them with alternative products such as foods.

The benefits from the proposed regulation and the regulatory options result from reducing contamination and adopting practices that will result in consistently high quality dietary supplements. Creating industry-wide minimum requirements for good manufacturing practices should reduce the occurrence of product defects, which in turn should reduce the number of illnesses and deaths.

Defective products can cause isolated cases of illnesses, but also rare catastrophic events such as the outbreak of eosinophilia myalgia syndrome (EMS) that resulted from the consumption of contaminated L-Tryptophan. That outbreak caused 38 deaths and over 1,500 illnesses.

The provisions that require establishments to maintain consumer complaint files related to manufacturing practices will generate additional health benefits. The use of these files by manufacturers and the agency will help identify dietary supplements that were manufactured or contaminated in ways that could cause a significant or unreasonable risk of illness or injury. These records may reduce the likelihood of catastrophic events, because a cluster of illness complaints could be identified, and preventive action taken before the number of illnesses reached catastrophic levels.

Improved product quality will also reduce the number of products recalled. Certain manufacturing practices, such as more frequent finished product quality testing, help establishments to identify problems before the products are released for consumption. If defective products are caught before they are released, they will not be recalled.

Creating minimum requirements should also generate benefits for consumers by reducing the variation in product quality. Creating verifiable minimum manufacturing requirements reduces the private effort necessary to distinguish products manufactured, packaged, and held using good practices from those using poor practices. Reducing the effort needed to find products with the identity, purity, strength, quality, and composition, among other characteristics, creates a potentially substantial, though implicit, benefit for consumers.

The benefits from the proposed rule, then, are from:

- Reduced health costs caused by the reduced number of illness;
- Fewer product recalls, and;
- Greater assurance of consistent and better quality products.

a. *Reduced illnesses.* The proposed regulation would improve the safety of dietary supplements, which would reduce the number of illnesses and the probability of deaths caused by manufacturing problems. The proposed rule would also improve product safety through the provisions requiring records and investigations of consumer complaints related to manufacturing practices. We assumed that the proposed rule would reduce both sporadic illnesses and catastrophic outbreaks. We estimated the reduction of sporadic or annual illnesses by using the agency's 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. 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.

i. *Reduced illnesses estimated from recall data.* For annual illnesses, we used this formula for estimating the benefits from fewer illnesses:

*Marginal health benefits = baseline (or current) number of illnesses caused by poor manufacturing practices × expected reduction in the number of illnesses brought about by the proposed regulation × health cost saved per prevented illness.*

We estimated the annual expected health benefits for the proposed rule by taking the values in table 8 of this document and weighing them by their incidence in the table. We computed the expected health benefits from preventing a single illness (of any type) associated with a class 1 recall as a weighted average of all potential illnesses (see table 8 of this document), with the potential illness divided by the total number of class recalls.

The following formulas show how we calculated the average health benefits of preventing a single illness associated with a class 1 recall.

$\$health_{ij} = (QALD \times days \times \$ \text{ per } QALD)_{ij} + \$ \text{ medical}_{ij}$

$EB_j = \Sigma_i (f_{ij} \times \$health_{ij})$

$EB\ [c1] = \Sigma_j (w_j \times EB_j)$

$w_j = r_j/(\Sigma_j r_j)$

Where:

$\$health_{ij}$ = health costs of severity level i of illness j;

QALD = quality adjusted life day;

$ per QALD = dollar value of a statistical day;

$ medical = direct medical costs;

$Eb_j$ = expected health benefit from preventing a single case of illness j;

$f_{ij}$ = frequency of severity i of illness j ($\Sigma f_{ij} = 1$);

m = number of levels severity for illness j;

EB [c1], EB [c2] = expected benefits from preventing an average illness associated with a class 1 recall or a class 2 recall;

$w_j$ = weight of illness j;

$r_j$ = number of product recalls for hazard j;

n = number of hazards or potential types of illness.

We then repeated the procedure for class 2 recalls and the associated illnesses in table 8 of this document. Table 9 of this document shows the average value of preventing a single illness associated with class 1 and class 2 recalls.

We estimated the annual marginal health benefits as the health benefits per illness for each class of recall multiplied by the estimated number of recalls.

*Health Benefits = (EB[c1] × estimated annual number of class 1 illnesses prevented) + (EB[c2] × estimated annual number of class 2 illnesses prevented).*

To estimate the number of illnesses prevented, we started with the average annual number of products recalled for the decade 1990 to 1999—six class 1 and seven class 2. As discussed above, we then assumed that these recalled products represented proxies for about 1 percent of all illnesses caused by these problems leading to the recalls. With that assumption, we get 600 illnesses from class 1 recalls and 700 illnesses from class 2 recalls (see table 9 of this document).[6]

Table 9 of this document shows the estimated value of the health benefits from the proposed rule using class 1 and 2 recall data.

TABLE 9.—HEALTH BENEFITS USING RECALL DATA

| | |
|---|---|
| Total number of illnesses prevented, recall base | 1,300 |
| Total number of illnesses associated with class 1 recalls | 600 |
| Total number of illnesses associated with class 2 recalls | 700 |

[6] 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 number of recalled products were reported cases and that the probability of reporting equaled 1 percent (Ref. E16). The result is that the mean estimated number of illnesses is 100 times the reported number of recalls.

TABLE 9.—HEALTH BENEFITS USING RECALL DATA—Continued

| | |
|---|---|
| Dollar estimate of health benefit for preventing an illness associated with a class 1 recall | $60,000 |
| Dollar estimate of health benefit for preventing an illness associated with a class 2 recall | $5,000 |
| Dollar estimate of annual health benefits, recall base (million) | $39 |

ii. *Health benefits from preventing a rare catastrophic event.* We estimated the marginal health benefits from reducing the probability of a catastrophic event as follows:

*Marginal health benefits = Change in probability of rare catastrophic event caused by poor manufacturing practices brought about by the proposed regulation × the number of illnesses caused by the rare event × health cost saved per illness.*

In 1989, there was a widespread outbreak of EMS resulting from consumption of contaminated L-Tryptophan. More than 1,500 cases (175 acute illnesses and 1,287 chronic illnesses) and 38 deaths were identified in 50 states (Refs. E21 and E22). The outbreak prompted a recall of all dietary supplements that contained more than 100 mg per daily dose, which later was expanded to almost all products containing L-Tryptophan. We used the public health cost of this event as an estimate of the cost of a future rare catastrophic event associated with dietary supplements.

EMS is characterized by severe myalgia and elevated eosinophils counts. Some of the most common symptoms are fatigue, weakness, fever, and arthralgia. Although a repeat of the EMS outbreak is not expected, it is an example of the rare, catastrophic events that should be prevented or mitigated by the proposed CGMP regulation. The testing provisions of the proposed regulation should reduce the probability that contaminated ingredients would be released to the public. The provisions for keeping complaint files and investigating complaints would allow more rapid identification of a major health event; the defective products could be identified and withdrawn well before the event claimed as many victims as L-Tryptophan.

To estimate the benefits from preventing reduction in the probability of a rare catastrophic event occurring, we first estimated the period between now and the last rare catastrophic event, 1989, and we needed to make baseline assumptions about the likely time interval between events. The last catastrophic event occurred over 13 years ago, so we assumed that the lower bound would be 50 years. For lack of data, we then assumed a uniform probability distribution between these two bounds, which leads to a rough estimate of once in 30 years. We do not know how likely rare events are, nor do we actually know the likelihood of reducing these events by the proposed regulation. There can be no conclusive empirical support for the likelihood of a future event because the past may not predict the future in the absence of a stable frequency distribution that reflects a statistically significant number of similar events. All we know is that such an event occurred at least once in the recent past, and remains a possibility. We recognize that our lack of information about such events creates significant uncertainty about the social costs of these events and the health benefits from reducing their impact. Our estimate is meant to convey the potential or hypothetical enormity of such an event, not the certainty of such an event. We would like comments regarding our estimate of such an event.

The health cost of the EMS outbreak was large because of the number, severity, and duration of the cases. One followup study (Ref. E21) found 88 percent of EMS patients were still symptomatic 21 to 64 months after onset. The symptoms associated with EMS also frequently lead to activity limitations. Another study of victims (Ref. E22) found that 74 percent of symptomatic EMS sufferers were limited in their functions 12 months after the onset of illness.

To find the health cost of the outbreak, we estimated the cost of the following health outcomes: Death, acute illness only, chronic illness with no activity limitation, chronic illness with mild activity limitation, chronic illness with moderate limitation, and chronic illness with severe limitations. To determine the cost for each of these health outcomes, we multiplied the lost quality-adjusted life days over the duration of the illness by the value of a life day. For medical costs, we estimated the cost of hospitalization for the EMS patients who required hospitalization (32 percent of all victims), by assuming 3 days per hospital stay. We used $1,284 as the cost per day of time spent in a hospital (Ref. E17). We assumed that chronic sufferers visited the doctor once a year at a cost of $84 per visit. We estimated the total cost of the event to be about $2 billion. Most of the cost of the outbreak comes from the deaths and severe chronic illnesses. Table 10 of this document shows the values used in the calculation. Note that the categories are not mutually exclusive. The average age of victims was about 50, so the value of statistical life was adjusted accordingly. If the event occurs about once in 30 years in the absence of the proposed rule, then the expected average annual cost would be about $66 million.

TABLE 10.—HEALTH BENEFITS FROM PREVENTING RARE CATASTROPHIC EVENT

| | Number | Costs per case |
|---|---|---|
| Hospitalization | 480 | $3,741 |
| Death | 38 | 4,214,301 |
| Acute Illness | 175 | 8,760 |
| Chronic illness not limited | 380 | 1,091,849 |
| Mild chronic illness, limited | 190 | 1,349,002 |
| Moderate chronic illness, limited | 307 | 1,601,539 |
| Severe chronic illness, limited | 409 | 1,602,844 |
| Visits to physicians | 1,287 | 1,539 |

The benefits attributable to this proposed rule from preventing a rare catastrophic event are highly uncertain. We do not know if such an event would, in the absence of the proposed regulation, ever occur again. The EMS outbreak may have been a unique event, although the recent severe public health effects associated with aristolochic acid in Europe show that such similar events remain possible (Ref. E23). We also do not know that if another catastrophic event occurred, the health effects would be as large as for L-Tryptophan. Some of the smaller clusters associated with dietary supplements could represent small events potentially prevented by the proposed CGMP regulations (Ref. E15).

We included reducing the likelihood of a catastrophic public health event as a benefit of the rule because the battery of checks and controls that would be required under the proposed regulation would reduce the likelihood of such an event occurring again. In particular, the requirement that establishments keep records of consumer complaints should lead to early identification and prevention of potential catastrophic events related to manufacturing practices.

Our estimate of the health benefits associated with this proposal is based on two models that estimate future illnesses and deaths prevented by this proposed rule: Illnesses caused by sporadically adulterated products and predicted by recall data; and rare catastrophic outbreaks of illnesses, as predicted by one previous event in the United States and corroborated by one in Europe. The frequency and magnitude of a rare catastrophic event is largely hypothetical. In contrast, sporadic illnesses are small but frequent events that happen routinely. Small sporadic events are characterized by significant underreporting primarily because of the difficulty linking an illness with the cause of an illness. Determining the cause of an illness in small sporadic events is made even more difficult because only the most serious illnesses are likely to be reported and because of the difficulty of linking the cause of an illness with poor manufacturing practices. Catastrophes are large but infrequent events that create hundreds of illnesses with reporting that is close to complete because the public health system typically devotes considerable care in identifying the origin and magnitude of the problem. Adding these two models should not lead to double counting the health benefits. Double counting would most likely occur if a recalled product caused both sporadic illnesses and a catastrophic number of illnesses and the public health system accurately recorded the full number of both sporadic and catastrophic illnesses.

b. *Fewer products recalled.* Implementation of the proposed regulation would reduce the number of adulterated products distributed to the public, which would reduce the number of products recalled. Manufacturing practices, such as testing of finished products and better recordkeeping, will increase the ability of establishments to identify problems before products are released for distribution. If adulterated products are caught before they are distributed, they will not be recalled.

To estimate the direct benefits from fewer recalled adulterated dietary supplements, we estimated the baseline number of annual recalls of dietary supplements due to contamination before the proposed regulation. From 1990 to 1999, FDA received reports on an average of 20 recalls per year (Ref. E12). 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 recalled product of 1,000 units to 34,000 units (Ref. E12). Product price also varied, with most prices falling between $5 per unit and $9 per unit; we used a most likely price of $7.70 per unit. We also included an adjustment for the goodwill lost by the establishment as a result of the recall. Studies of changes in market valuations of firms after recalls indicate that the value of lost customer goodwill, based on the decline of the share price of publicly traded stocks from recalls is often as large as the cost of the recall itself (Ref. E24). We multiplied the direct cost of the recall by two in order to include the lost goodwill. The result is an estimated savings of about $3 million per year.

We based the estimated benefits from fewer recalled products on our recall data. If there were private recalls due to contaminated supplements that were not included in our data, the benefits from reduced recalls may be understated.

c. *Reduced hypothetical search costs as a measure of the benefit from increased assurance of quality.* Consumers incur a cost if they purchase products but do not get the quality of product they anticipated. Determining the cost they incur is difficult, because we cannot look at the price of poor quality products and conclude that consumers paid too much, even when they did not get the quality they anticipated. We cannot disentangle the price consumers are paying, from the price they should be paying, because we assume consumers expect some unknown number of their products may not meet their expectations but purchase them anyway. In other words, we cannot rule out the possibility that the purchase price already incorporates the expectations of consumers that some products will be ''lemons.'' Because we cannot look into the minds of consumers to determine their expectations or their willingness to pay for these products, we can only estimate the benefits from more uniform quality by estimating the changes in behavior that would occur if consumers were aware of the change in quality brought about by the proposed rule. In other words, we assume that if the quality attributes of dietary supplements were observable, then consumers would spend time searching for those attributes, as they do for other goods. We measured this benefit as a reduction in the hypothetical search costs for product quality, meaning the identity, quality, purity, strength, and composition claimed on the label.

The hypothetical measure of quality starts by assuming the existence of a baseline amount of search necessitated by the existence of poor manufacturing practices. Our hypothetical consumers must search for products made with good manufacturing practices, because they cannot take such practices for granted when purchasing dietary supplements. Although the search we use as a measure of the benefits from improved quality is hypothetical, the values we use in estimating our search model are based on data and inferences about real searches for other products.

To get the products they want, people search across the range of market alternatives. Several recent articles have noted the large variation in product quality for different goods and services (Refs. E25, E26, and E27). Searching takes time and resources that could be used for other purposes, so a regulation that reduces search provides measurable benefits to consumers. To reduce the effort devoted to searching, consumers of dietary supplements should therefore be willing to pay some amount. We lack, however, a measure of what they would be willing to pay, partly because some consumers may not know that dietary supplements may contain more or less (or something not even expected) of what they think they are buying. Indeed, if consumers of dietary supplements could determine the quality of these products by merely examining the product or the label, the market alone would be sufficient to ensure that firms responded to consumer preferences for product quality. Consumers would search for those brands that are more

likely to have the desired quality, and manufacturers would most likely adopt sufficient quality controls to satisfy consumer preferences. The market response is weak now because only some consumers know that product quality problems exist, and even these consumers must rely on imperfect information. If there were uniform quality control practices throughout the industry that ensured against product quality defects, consumers would not have to search for the products that they believe are free from contamination or have the identity, purity, strength, quality, and composition they want. Consumers could more reasonably assume that all products are free from contamination and have the identity, purity, strength, quality, and composition stated on the label.

We faced the problem of trying to measure what people would pay for more uniform products quality if they knew that manufacturing quality requirements did not already exist. To estimate what people would pay, we start with the hypothetical behavior of people aware of the lack of uniform product quality; we call these hypothetical people the ''sophisticated consumers.''

Sophisticated consumers spend time searching for signals about the quality of dietary supplements. The proposed CGMP regulations would reduce the amount of search (by some uncertain amount) carried out by these consumers. The benefits of the rule, however, would not be confined to sophisticated consumers. We also expect ''naive consumers'' to enjoy the benefits. Naive consumers would incur the costs of additional search once the correct or adverse information about quality is available, suffer from worry or an illness from taking poor quality products, or incur the cost of paying for products that do not meet their needs (Ref. E28). Once good practices are in place they would avoid these costs. Naive consumers are those who fail to search for quality or search little not because they do not care but because they do not know that quality varies as much as it does. In other words, they lack the information that problems exist; if they know about the problems, they would search or be willing to pay more to ensure that supplements they consume meet minimum quality standards. Although these naive consumers may not change their behavior in response to the proposed CGMP regulation, they would nonetheless enjoy the benefits. The naive consumers, of course, also represent real consumers of dietary supplements. The total benefits of the quality standards part of the proposed rule will be the implicit value of the gain in product quality enjoyed by all consumers.

The problem is to measure that gain based on hypothetical searches. We needed to use data from searches in other markets, because we found no information on direct or indirect searching for minimum dietary supplement quality standards. For the sophisticated consumer, we assumed that the value of search time should be approximately the same as the willingness to pay for an attribute of the good. Sophisticated consumers will hypothetically search until the expected benefit of continued searching is less than the expected cost of continued searching. The total cost of search time will, on average, be no more than the expected cost of the additional quality desired. Search time includes the time spent: Reading product labels and other literature about the product, comparing one product with other products, examining the product itself (sometimes carefully), thinking about the product, and second guessing final decisions. It might also include the time actually shopping for the product: Finding the locations where the product is sold, driving there and back, waiting in checkout lines, and walking up and down the aisles.

We used information on shopping times for a range of products to derive an estimate for the hypothetical search time for dietary supplements. We assumed that some fraction of shopping time is pure search time, although we also recognize that search time includes more than the search for product quality. Some search time, for example, is for price, efficacy, and other attributes. The reduction in search time for the sophisticated consumer would therefore be at most a fraction of total search time for dietary supplements. The measure of time saved then is:

Reduced search time due to CGMP regulation = shopping time × fraction of shopping time spent searching × fraction of search time associated with searches for quality × fraction of search time associated with searches for quality that would be eliminated if CGMP rule guaranteed minimum quality.

We took the estimated reduction in hypothetical search time for the sophisticated consumer and applied it to all consumers to get an estimate of the implicit benefits of establishing minimum quality standards. This estimated saving in hypothetical search time is not a forecast of reduced shopping time; it is a proxy measure of the benefit from reduced variance and improved mean product quality. We anticipate little or no change in aggregate shopping time for dietary supplements.

We converted the time measure into a monetary measure by multiplying the time reduction for sophisticated consumers by the average wage rate. The benefits measure reduced search time associated with improved quality assurance:

Quality assurance benefits = reduction in search time (in hours per year) per sophisticated consumer × average wage rate per hour × total number of consumers.

The shopping time model is an indirect approach to measuring benefits in a market with asymmetric information; it is not a prediction about how shopping behavior will change in that market. Indeed, we believe that most of the beneficiaries of this part of the rule will never recognize that they are beneficiaries.

Standardization imposes minimum requirements on manufacturing, which in turn should reduce the variance of product quality. The reduction in product quality variation should reduce the amount of information sophisticated consumers need to acquire before purchasing dietary supplements (Ref. E29). People need not rely as much on such indicators as brand names, price, place of purchase, articles in consumer magazines, or advertising to determine the likelihood that dietary supplements meet minimum quality standards.

Although no studies deal with dietary supplements directly, the literature on consumer search for other commodities provides insights that increase our understanding of the search costs for supplements (Refs. E30 and E31). Duncan and Olshavsky (Ref. E32) surveyed buyers of television sets and found that 88 percent of respondents performed some type of search activity before purchase. In a study (Ref. E33) of consumer search for microwave ovens, the average buyer of a new microwave oven was willing to search for four alternative products. Search for groceries has been characterized as a two-stage process (Ref. E34). First, people engage in prestore activities, such as reading advertisements, writing shopping lists, clipping coupons, and comparing stores. Second, people engage in search activities at the store, including price and product comparison and search for items with coupons. Most people devote time to search activities for all but the most routine purchases.

To estimate the reduction in hypothetical search costs from the proposed rule, we started with estimates

of the time consumers spend in search for groceries and other household purchases (including durable goods). We assumed that the search time for these products was related to shopping time. Because search costs include the costs of evaluating magazine articles or brochures, the costs of obtaining a friend's advice, and the costs of instore product comparisons, our estimates will not correspond precisely to the actual costs of search for these products (Ref. E35). We believe, however, that the measure will be a reasonable approximation. Although search time often takes place outside of measured shopping time, measuring search time as some proportion of total shopping time should generate a plausible if not a precise estimate.

We generated three models of search time for dietary supplements, based on three separate studies of shopping time:

- Drug Store.
- Use of Time.
- Grocery Store.

We used three models based on different assumptions because using a range of studies reduced the likelihood of systematic bias in our analysis.

*The drug store model.* The drug store study recorded the amount of time people spent looking at an item on the shelf before making a purchase (Ref. E36). Customers, on average, spent 3.75 minutes studying a product before purchasing it. Although there are quality standards in place for over-the-counter drugs and not for dietary supplements, we assumed that this represented a measure of the amount of time the sophisticated consumer might spend searching for a product with the desired quality.

*The use of time model.* The Americans' Use of Time Project (Ref. E37) used time diaries to study how adults spent all of their time. The study collected data from over 3,500 adults on use of time. Data from these time diaries reveal that adult Americans spent about 364 minutes per week shopping for personal consumption items, such as groceries and other household products.

*The grocery store model.* In the grocery store study, hidden observers tracked and recorded shopping time in the store (Ref. E38). The study found that people on average spent about 21 minutes shopping in the grocery store. By combining estimated time per trip with the Food Marketing Institute's (Ref. E10) finding that consumers average about 2.2 grocery shopping trips per week, we generated an estimate of search time for all grocery store purchases of 46.2 (= 2.2 × 21) minutes per week.

For each of the models, we needed to make assumptions to convert shopping time for other commodities into search time for dietary supplements. Table 11 of this document shows the assumptions and information used in each model.

TABLE 11.—THREE MODELS OF SEARCH TIME: ASSUMPTIONS USED IN SIMULATIONS

| Variable | Value or distribution | Source and notes |
|---|---|---|
| **Drug Store Model** | | |
| Search time in minutes per item | 3.75 | Ref. E30. |
| Number of products per person per year | 6.57 | Ref. E4. |
| Average wage rate | $15.65 per hour, or $0.26 per minute | Ref. E42. |
| Population | 273 million | Ref. E19. |
| Fraction of search time devoted to searching for quality. | 0.2 (based on uniform distribution, 0.1 to 0.3) | Based on number of attributes consumers search for. |
| **Use of Time Model** | | |
| Weekly shopping time for all items in minutes | 346 | Ref. E37. |
| Fraction percent of budget spent on supplements. | $15.5 billion/$6,250 billion | Ref. E4 and E19. |
| Average wage rate | $15.65 per hour, or $0.26 per minute | Ref. E42. |
| Adult population | 205 million | Ref. E19. |
| Ratio of search time to shopping time | 0.7 (based on uniform distribution, 0.4 to 1.0) | Based on descriptions of shopper behavior. |
| Fraction of search time devoted to searching for quality. | 0.2 (based on uniform distribution 0.1 to 3.0) | Based on number of attributes consumers search for. |
| Potential reduction in search time attributable to CGMP regulations. | 33% most likely (could be between 15 and 50%). | Based on likelihood of problem and likelihood that search will decline proportionally, and the expert opinion of pharmacists. |
| **Grocery Store Model** | | |
| Weekly shopping time for groceries in minutes | 46.2 | Ref. E38. |
| Ratio of supplement expenditures to grocery expenditures. | $15.5 billion/$710 billion | Ref. E38. |
| Average wage rate | $15.65 per hour, or $0.26 per minute | Refs. E4 and E19. |
| Adult population | 205 million | Ref. E19. |
| Ratio of search time to shopping time | 0.7 (based on uniform distribution, 0.4 to 1.0) | Based on descriptions of shopper behavior. |
| Fraction of search time devoted to searching for quality. | 0.2 (based on uniform distribution, 0.1 to 0.3) | Based on the number of attributes that consumers search for. |
| Potential reduction in search time attributable to CGMP regulations. | 33% most likely (could be between 1% and 50%). | Based on likelihood of problem, the likelihood that search will decline proportionally, and the expert opinion of pharmacists. |

The drug store data generated a direct estimate of search time. In the drug store model we assumed that the time spent standing in front of the drug product could be used to estimate the time searching for dietary supplements. We then used data on the number of products purchased per person and the total U.S. population to generate an estimate of annual search time for dietary supplements.

To estimate the time spent searching for supplements from the use-of-time study, we assumed that the share of all shopping time devoted to supplements would be proportional to the share of a consumer's budget spent on supplements. We recognize that it could well be higher if supplements require more search than the average commodity. According to an industry source and FDA projections, consumers spent about $15.5 billion on dietary supplements in 1999 (see table 5 of this document). Consumers spent about $6,250 billion on all personal consumption in 1999, which means that dietary supplements accounted for about 0.24 percent of those expenditures. Personal consumption expenditures included in this estimate are food, alcoholic beverages, housekeeping supplies (such as laundry and postage), household furnishings and equipment (such as furniture and appliances), apparel (includes footwear), personal care products and services, reading materials, tobacco products, and smoking supplies. Annual shopping time per person for dietary supplements would therefore be about 44.6 minutes per year (= ($15.5 billion/$6,250 billion) × 346 minutes per week × 52 weeks). We converted shopping time to search time by assuming that search time equaled 40 to 100 percent of shopping time. Total search time equaled search time per adult multiplied by 205 million adults. We assumed that all adults would perform search, although we recognize that not all adults consume dietary supplements and not all search is conducted by adults. Children might search for these products also. The opportunity cost for children, as measured by their wage rate is much less than for adults, so we assumed their search time could be ignored. We used the total adult population rather than just the adult consumers of dietary supplements, because the shopping time studies are for all adults.

We estimated search time in the grocery store model with assumptions similar to those in the use-of-time model. We assumed that the ratio of search time for supplements to search time for groceries would equal the ratio of expenditures on supplements to expenditures on groceries. Estimates from the 1998 Consumer Expenditure Survey (Ref. E39) (adjusted for changes in prices between 1998 and 1999) reveal that consumers spent approximately $710 billion on grocery store purchases in 1999. Grocery store purchases included food, alcoholic beverages, housekeeping supplies, personal care products, tobacco products, and smoking supplies. Annual shopping time per person for dietary supplements would therefore be about 52.5 minutes per year (= ($15.5 billion/$710 billion) × 46.2 minutes per week × 52 weeks). We again converted shopping time to search time by assuming that search time equaled 40 to 100 percent of shopping time. Like the estimate from the use of time model, this value was then multiplied by 205 million adults.

We used these three models based on different assumptions because we wanted to explore a range of studies to avoid systematic bias in our analysis. We recognize that the three estimated annual search times for dietary supplements do not represent the search for quality alone. Consumers search for a variety of features; only part of every search will be devoted to quality. We assumed that 10 to 30 percent of pure search time involves quality searches. Estimating the impact of CGMP regulations on consumers' search time is difficult, since no previous studies have analyzed the changes in search time following the adoption of CGMP regulations or from increases in product quality standardization. However, a consistent finding from the literature is that search time should decline following a decrease in the variation in product quality (Refs. E35 and E40). In the absence of previous empirical studies, we assumed that the proposed rule would reduce the hypothetical search time for quality ''the search time of sophisticated consumers'' by 1 to 50 percent, with 33 percent the most likely value. A survey of pharmacists reported their belief that 30 percent of their customers place manufacturing quality as a top priority in selecting one herbal over another (Ref. E41). We also used evidence from product tests that indicated that up to 33 percent of products were missing key ingredients or contained unwanted ingredients (Refs. E25, E26, and E27). If the proposed rule guarantees that products will contain what the label claims, then perhaps search time for quality will decline by that percentage.

To estimate the value of the possible reduction in searching for quality, we multiplied our estimated time saving by the average wage rate, which is an estimate of the value of time. The average hourly wage rate for U.S. workers was $15.65.[7] We ran computer simulations of all three models. The results for the three models are shown in table 11 of this document.

d. *Other benefits.* The proposed regulation could also reduce the total time and effort that all covered establishments expend to monitor ingredient suppliers and holders of their products. Because all ingredients and holders would be subject to the same uniform minimum requirements, variation in their practices would decline, so firm monitoring of upstream and downstream vendors could decline.

The provision that requires establishments to maintain complaints files would allow a manufacturer to more readily be able to identify a product that causes a significant or unreasonable risk of illness or injury. The manufacturer can then take necessary steps to prevent any additional adverse health impact. We have attempted to quantify this benefit for preventing catastrophic events, but not for reducing smaller risks. FDA adverse event reports, however, imply that many such small events occur, and the proposed rule could prevent some of them (Ref. E15).

In addition, if the same adverse events show up in complaints received by different firms selling products with the same or similar manufacturing problems, no one firm selling such products may recognize the need to investigate the complaints especially if the risk is relatively low. Because we would have access to complaint files, our review would be more likely than any individual firm's review to identify the need to investigate the complaint because of a reasonable possibility of a relationship between the manufacturing process of a dietary supplement and the adverse event.

e. *Total measured benefits.* The total measured benefits from the proposed rule are the sum of the value of health benefits, the value of the reduced number of product recalls, and the reduction in hypothetical search costs. Table 13 of this document shows the total benefits.

TABLE 12.—THREE MODELS TO ESTIMATED SEARCH COST SAVINGS

| Baseline model | Cost savings (in millions) |
|---|---|
| Drug store model | $108 |
| Use of time model | 101 |
| Grocery store model | 119 |
| Average of three baseline models | 109 |

[7] Personnel Employment, Hours, and Earnings. Series ID: EES00510006 Seasonally Adjusted, Industry: Goods-producing Data Type: Average hourly earnings of production workers, Employment Cost Index, Bureau of Labor Statistics.

TABLE 13.—SUMMARY OF ANNUAL BENEFITS

| Benefits | Mean (in millions) |
|---|---|
| Fewer illnesses (from table 8) | $39 |
| Fewer illnesses (from table 10) | 66 |
| Fewer product recalls (from table 9) | 3 |
| Reduced consumer search (from table 12) | 109 |
| Total benefits | 218 |

7. Costs

The same changes in practices that produce benefits also have costs, the opportunity costs of not doing what consumers and manufacturers are now doing. The proposed regulation would require dietary supplement establishments to adopt some new practices in order to manufacture, package, and hold their products. The costs incurred for those who choose to comply will be for personnel, grounds and physical plant, equipment and instrumentation controls, quality control and laboratory operations, production and process controls, handling consumer complaints, and holding. In some cases, establishments would need to make capital improvements to the physical plant, add or replace equipment or controls, perform additional maintenance, keep records, carry out tests, or execute a variety of additional tasks that they may not have previously performed. We estimated the additional costs of production associated with the proposed rule and the leading regulatory options, using the survey (Ref. E2) to estimate baseline manufacturing practices.

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).
- Large (500 or more).

Although this consolidation glosses over the important differences across products, the purpose is to estimate the broad average costs of the rule.

For each category, we constructed a cost model that included every provision of the CGMP regulations that the proposed rule requires or recommends. We then attached a cost to each provision that had an activity associated with it. Most provisions did not have costs attached to them, mainly because they were either descriptive or the costs were included elsewhere. For the rule as a whole, we estimated the marginal, or additional costs for over 70 provisions of the proposed rule.

We expressed the cost as cost per unit, with the unit being either the establishment, the number of employees, or the annual number of batches produced. The costs of this proposed rule included the following general activities: Sanitation, production and process controls, holding and distributing, and consumer complaints.

b. *Costs of general activities.* i. *Sanitation.* Sanitation includes both one-time capital improvements and ongoing efforts. Some provisions of the proposed regulation may require establishments to perform one-time capital improvements to their physical plant facilities.

The proposed regulation would also require, if not already in place, physical plant owners to install new or additional plumbing systems to carry additional water or sewage, additional toilet or hand washing facilities, additional facilities for trash disposal, or new signs to instruct employees. The proposed regulations might also require establishments to add space in order to keep equipment and materials farther apart, which will help to prevent contamination or mixups. Other possible capital expenditures (among many other possible requirements) include:

- Replacing floors, walls, or ceilings with smooth, hard surfaces;
- Changing fixtures, ducts, or pipes that might be a source of contamination by dripping or condensation;
- Adopting ventilation control systems including filters, fans, or other air-blowing equipment to prevent odors or vapors;
- Additional lighting to ensure that equipment, contact surfaces, or other areas where supplements are examined, processed, or held can be adequately seen.

Sanitation also requires that equipment utensils must be of suitable design, construction, and workmanship to enable them to be adequately cleaned and maintained. To meet this requirement, some establishments may need to provide additional maintenance or additional cleaning and sanitation for their equipment and utensils. Also, freezers and cold storage compartments used to slow or arrest the growth of microorganisms must be fitted with thermometers to accurately show the temperature within the compartments. Instruments and devices used in manufacturing must be accurate, adequately maintained, and adequate in number. To meet this requirement establishments might have to purchase new equipment, replace old equipment, or provide additional maintenance to existing equipment.

ii. *Production and process controls.* Production and process controls are the main preventive mechanism to ensure the identity, purity, quality, strength, and composition in the proposed rule. Establishments must implement a system of production and process controls that covers all stages of processing, from the receipt and acceptance of components, dietary ingredients, dietary supplements, packaging, and labels through the release for distribution and holding of the dietary ingredients and dietary supplements. Establishments must identify points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration. Establishments must also establish specifications for the identity, quality, purity, strength, and composition of components, dietary ingredients, or dietary supplements. Establishments must monitor the points, steps, or stages in the batch production, as specified in the master manufacturing record, where control is necessary to prevent adulteration. Establishments must establish specifications for packaging to ensure that containers or closures that come into contact with dietary ingredients or dietary supplements are not reactive or absorptive and are composed of substances that are safe for use in or on food.

Establishments that have not already done so must establish a quality control unit with one or more individuals that have with the authority and responsibility to review the results of monitoring, make decisions on the disposition of materials, and identify whether actions taken to correct any deviations are appropriate. The quality control operation must ensure that components, dietary ingredients, and dietary supplements conform to specifications.

iii. *Holding and distributing.* Establishments must hold and distribute dietary ingredients and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, quality, purity, strength, and composition of the dietary ingredients and dietary supplements are not affected. Establishments must also identify and

hold components, in-process materials, and dietary supplements under conditions that will protect them against mixups and physical, chemical, and microbial contamination. Packaging materials must also be protected against deterioration. Establishments that do not now perform these requirements and the other provisions associated with holding will incur a compliance cost.

iv. *Consumer complaints.* The quality control unit must review all consumer complaints involving the failure of a dietary supplement to meet any of its specifications, or the failure to meet any other requirements under proposed part 111, including those specifications and other requirements that, if not met, may result in possible illness or injury. In addition, the quality control unit must investigate such a consumer complaint where there is a reasonable possibility of a relationship between the consumption of a dietary supplement and an adverse event. The complaint and report of the investigation results should be reported to FDA when there is a possibility of a serious adverse event.

c. *Major costs by type of activity.* Within these four categories (sanitation, production and process controls, holding and distributing, consumer complaints), the major costs of the proposed rule are recordkeeping (except for sanitation), capital costs for physical plant and equipment, finished product quality testing (part of production and process controls only), labor costs for certain required tasks, and some other costs that were not easily classified.

i. *Recordkeeping.* We used a study of a medical device CGMP regulation to estimate the costs of recordkeeping (Ref. E44). We request comments on the applicability of a study of the medical device CGMP's to dietary supplements.

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 mandatory records is a recurring cost that depends on how frequently records are modified, the frequency of personnel turnover, and how complicated the tasks are that are being recorded. The recurring costs are measured by the workers' wage rate, which we assumed is $15.65 per hour based on the average manufacturing wage, multiplied by the expected labor hours necessary to perform a written or electronic record and the time necessary for management to review the records to see the actions are documented accurately. For electronic records, the recurring time is the time necessary to ensure that the equipment is serviced and maintained properly.

ii. *Capital costs for physical plant and equipment.* We estimated capital costs for physical plant redesign at $50 per square foot (Ref. E45). For establishments with inadequate facilities, we assumed that between 0 and 20 percent of the physical plant would have to be renovated, with 10 percent the most likely. For equipment costs, we assumed that very small establishments would on average spend 0 to $1,000, with $100 the most likely amount. Small establishments would bear costs 3 times that of very small establishments, which is the ratio of the size of the physical plants of small establishments to the size of the physical plants of very small establishments. We assumed that large establishments would bear (if necessary) costs 20 times that of very small establishments, which is the ratio of the size of the physical plants of large establishments to the size of the physical plants of very small establishments. In other words, we assumed capital costs for physical plant and equipment would be proportional to facility size, as measured in square feet.

iii. *Testing.* Establishments that do not already conduct the required product quality tests of each batch of dietary ingredients or dietary supplement produced would incur the cost for those tests. Under the option for more restrictive CGMP rules, each lot of components would also be tested. The costs per establishment depend on both the number of tests and the costs per test. We did not estimate the cost of developing new, validated tests methods because we lacked information about the costs for this requirement and the number of such tests that need to be developed. We ask for comments on the costs to develop tests, for the number of tests and the costs for performing each test to comply with this requirement.

- Number of tests: Model. To estimate the costs of testing, we first estimated the number and costs of individual tests, without adjusting for the amount of testing already being done. In this section we show how we estimated the likely number of required tests, unadjusted for current voluntary testing. For a representative manufacturer, the annual number of tests would be the number of new tests per batch multiplied by the number of batches produced in a year.

The proposed rule requires only tests for identity, purity, quality, strength, and composition of the final product. The option for stricter CGMP regulations would also require tests of components. Estimating the number of component tests per batch is complicated, because component tests are made on the shipment lots, rather than on the parts of the lots that actually go into the final product. For example, if a lot of some ingredient is used in 6 batches of final products, it would probably be tested only once.

The establishment itself may test the shipment lots, and during inprocess stages for identity, purity, quality, strength, and composition, unless final product testing is done.

The number of component tests per batch of final product would equal the number of tests per component, multiplied by the number of components per batch, divided by the batches per shipment lot (to account for the production of multiple batches of dietary supplements from single lots of components).

The option for stricter CGMP regulations options would also require some inprocess tests upon receipt. The number of inprocess tests per batch is the same as the number of potential inprocess product defects. The estimated number of inprocess tests counts only tests for defects that can occur during production, not tests for the defects of dietary ingredients and components supplied to the producer.

We used the following formulas to estimate the number of tests:

$$\text{Component test per batch} = \left[\sum m_j\left(I_j \times R_j\right) + \sum_k^n\left(U_k \times R_k\right)\right] \times (S/B)$$

$$\text{Inprocess quality tests per batch} = \sum_1^o\left(H_1 \times R_1\right)$$

$$\text{Quality tests per batch of final product} = \max\left[m \times (1/z), 1\right]$$

Where:

$I_j$ = jth listed ingredient;

m = number of ingredients per batch;

$R_j$ = required tests for ingredient j;

$U_k$ = kth unlisted component (an inactive substance);
n = number of unlisted components per batch;
$R_k$ = required tests for unlisted component k;
S = number of shipments (or lots) of ingredients and unlisted components;
B = number of batches produced;
$H_1$ = 1th inprocess potential defects;
$R_1$ = required inprocess tests per batch for potential defect $H_1$;
o = number of potential inprocess defects per batch;
z = number of ingredients identified per quality test.

• Number of tests: Evidence and distributions. The quantity and quality of evidence on the variables used to estimate the number of required 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 ingredients. We based our measure of the number of dietary ingredients per product on a sample of almost 3,000 dietary supplement labels (Ref. E46). Although some dietary ingredients may be missing from the labels and some listed dietary ingredients may be missing from the products, the ingredient list represents the best evidence we are likely to have on what dietary ingredients are used in dietary supplements.

• Number of ingredients per batch. According to the sample of listed ingredients (Ref. E46). Vitamin and mineral products contain about 13 listed ingredients. Other dietary supplements, mainly herbals, contain about four.

• Number of tests per ingredient lot. The option for more restrictive CGMP regulations would require that virtually all dietary ingredients be tested for identity and defects at some stage between harvesting the raw product and the beginning of the production of the final product. We assumed one identity test per ingredient lot. The number of tests for defects depends on the number of possible defects, which can include: Filth; Microbial pathogens; Chemical hazards, including pesticides; Insects; Physical hazards, such as metals; Natural toxins, such as aflatoxin; and Inadequate purity, quality, strength, or composition.

The number of potential defects is potentially unlimited. As a practical maximum, however, few products would have more than five potential defects. In the calculation of ingredient testing costs (part of the option for more restrictive CGMP regulations), we assumed that the average number of tests per listed dietary ingredient would be between one and six: One identity test for identity, purity, strength, quality, and composition and zero to five tests for defects.

• 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. E47) says that four to six unlisted components are typical per product, although fewer are certainly possible. The minimum number is zero. We assumed that the number of unlisted components would be zero to six, with four the most likely.

• Number of tests per unlisted components. The unlisted components tend to be manufactured products, such as solvents. Therefore, one identity test would likely be sufficient.

• Number of shipments (or lots) of ingredients and unlisted components. We have no direct evidence on the number of shipment lots of dietary ingredients and components. We also have no evidence on the number of shipments per lot or on the number of shipments per batch. The increasing use of just-in-time inventory practices indicates that one shipment lot of components per batch may be the rule for some products and some producers. It is costly and difficult to store ingredients for an extended time, so establishments tend to buy more and smaller lots of components rather than a few large lots and storing them in bulk over an extended period (Ref. E48). Crude botanical and other ingredients are inherently unstable and may lose their quality in even a short time unless costly temperature, humidity, and light controls are in place (Ref. E49). We also know, however, that some dietary ingredient suppliers produce large amounts and then ship out smaller packages. For dietary supplements produced using part of a large production run of a dietary ingredient, the number of batches per lot could be large. Also, some producers buy a single 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. In the cost calculation, we assumed that 1 was minimum and 12 the maximum number of batches produced per lot, with 6.5 the average.

• Number of batches produced. We have survey results (Ref. E2) on the number of batches produced per establishment. According to the survey, very small establishments produce an average of 223 batches per year, small establishments produce an average of 554 batches per year, and large establishments produce an average of 309 batches per year.

• Inprocess potential defects. Inprocess defects involve many of the same potential defects that can occur in components. The more restrictive CGMP option requires inprocess tests at all points where contamination or other defects can occur. Filth, chemicals, microbial pathogens, physical objects, and insects can be introduced into the product during manufacturing. In addition, purity, quality, strength, and composition can be compromised.

• Number of potential inprocess defects. Some processes may have no control points, steps, or stages that involve the potential for defects. If certain manufacturing processes in the production of a dietary supplement can be carried out without being subject to potential defects, no inprocess tests would be required for those processes. We therefore assumed that zero inprocess tests would be the lower bound requirement. For the upper bound, we assumed that no products would have more than five potential control points or steps that could lead to defects. We believe that most production processes will have fewer than 5 control points, so we assumed an average of 2.5 control points requiring inprocess tests for defects.

• Number of required inprocess tests per control point. We assumed one test per defect per control point.

• Number of ingredients identified per quality test. We had no direct evidence on the number of identity tests per final dietary supplement. For the maximum, we assumed that the number of tests would equal the number of ingredients. The number of ingredients identified per test varies from less than one to a very large number. We assumed that for vitamins and minerals, the minimum number of identity tests would be one and the maximum would be 30, with 2 the most likely. Botanical and herbals are less easily characterized than vitamins; so identifying large numbers of ingredients with a single test would be highly unlikely. We assumed that one to two ingredients would be identified per test for herbal products.

• Number of final product tests per batch. We had no direct evidence on the number of quality tests per final dietary supplement. After adjusting for the possibility of multiple results from a single test, multiple ingredients in single products, and the differing number of ingredients in herbal and vitamin products, we estimated that the proposed rule would require about three tests for identity, purity, quality, strength, and composition for each batch of final product. These are the

only required tests in the proposed rule, but establishments may choose to perform inprocess tests and tests on ingredients in order to prevent waiting until final product testing to discover defects.

iv. *Costs per test.* We estimated the costs per test partly with published prices of independent laboratories as posted on the Internet (Refs. E50 and E51), and partly from our conversations with FDA and industry experts on testing. We found that 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 the taking and of samples, whose cost can vary.

We assumed that $20 per test represented a plausible lower bound. 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. Although some Internet testing prices for tests were 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 average cost per test was about $60.[8]

Changing our assumption about the midpoint of testing costs would change our estimate of the cost of the rule. If the cost of testing each batch is actually significantly higher, then the impact to those firms that incur the cost and to society will have been understated.

v. *The number and cost of tests: summary.* We estimated 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). We used survey responses to a question about the establishment's primary line of business for the weights used to compute the average number of tests. We dealt with multiple responses by treating all nonvitamin and nonmineral responses as other dietary supplements. The following weights, as shown below, differed 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.

The annual cost of testing differed by the size of the firm, because the average number of batches produced differed. For the option calling for more strict regulation, the total costs of testing would be much higher than in the proposed rule. The unadjusted total cost of testing under the more restrictive CGMP option would be:

$148,000 for very small establishments;
$415,000 for small establishments;
$263,000 for large establishments.

We estimate that the adjusted total cost for testing for the proposed regulation will be:

$11,230 for very small establishments;

$19,907 for small establishments;

$7,626 for large establishments.

We found some corroboration for these estimates in a comment on the Advance Notice of Proposed Rulemaking entitled ''Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements'' published in the **Federal Register** of February 6, 1997 (62 FR 5699 to 5709). According to the comment, the cost of testing components and final products inhouse would be at least $650 per batch plus microbiological tests. Testing costs could be more if establishments sent samples to independent laboratories for testing or if they conducted extensive identity tests of herbal and botanical products. If we apply the $650 to the annual number of batches per establishment, the comment implies that very small establishments would perform $145,000 (223 × $650) worth of tests, small establishments would perform $360,000 (554 × $650) worth of tests, and large establishments would perform $200,000 (309 × $650) worth of tests. These estimates are reasonably close to our simulation estimate.

The unadjusted testing costs represent the total requirements and recommendations, not the additional costs that would be incurred in response to the proposed rule. Tests on incoming components and inprocess tests would not be required by the proposed rule. Most establishments already conduct some tests, or send samples out for testing. We, therefore, adjusted the estimated testing costs of the proposed 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 14.—VALUES USED IN TESTING COST CALCULATIONS

| 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. E46). |

[8] The average cost is higher than the most likely cost because we modeled costs with a Beta-Pert distribution that was skewed rightward (toward higher costs). The Beta distribution is part of the Bernoulli family of distributions and is closely related to the Binomial. The Binomial gives the distribution of the number of successes (s) in n trials if the probability of the success in each trial is p. The Beta shows the distribution of the value of p when s successes occur in n trials. The Beta-Pert distribution is a Beta distribution that has been rescaled to run between values other than 0 and 1. The Beta-Pert uses a minimum, maximum, and most likely value to generate a distribution running from the minimum to the maximum, with a mean equal to (minimum + (4 × most likely) + maximum)/6. We used the Beta-Pert distribution because we did not have a representative sample to derive the distribution, but we did have enough information to identify a plausible maximum, minimum, and most likely value. The use of the Beta-Pert, then, indicates that we do not know the shape of the probability distribution of possible testing costs, but we do have limited data.

TABLE 14.—VALUES USED IN TESTING COST CALCULATIONS—Continued

| Name | Value or distribution used | Source |
|---|---|---|
| Number of identify tests per ingredient lot | 1 Identity test per ingredient lot | Assumption based on discussions with industry—FDA requests comments. |
| Number of tests for defects per ingredient lot | 0 to 5 tests for defects | Assumption based on discussions with industry—FDA request comments. |
| Number of unlisted components | 0 to 6 components; 4 most likely | Ref. E47. |
| Number of tests per unlisted components | 1 identity test per component | Assumption based on discusssions with industry—FDA requests comments. |
| 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—FDA requests comments (Ref. E48). |
| Number of batches produced | Very small establishments—223; Small establishments—554; Large—309. | Ref. E2. |
| Number of inprocess potential defects | 0 to 5 potential control points; 2.5 average | Assumption based on discussions with industry—FDA requests comments. |
| Number of inprocess tests per control point | 1 test per defect per control point | Assumption based on discussions with industry—FDA requests comments. |
| Number of ingredients identified per identity test | Vitamins and minerals—1 to 30; 2 most likely; All other categories—1 to 2. | Assumption based on discussions with industry—FDA requests comments. |
| Number of final product tests per batch | 3 tests batch | Assumption based on discussions with industry—FDA requests comments. |
| Costs per test | Beta per distribution skewed rightward between $20 to $150; $50 most likely; $60 average. | Refs. E50 and E51. |

vi. *Labor costs.* We used the average manufacturing wage of $15.65 per hour to estimate the cost of labor. We assumed that various tasks required by the proposed rule would take some number of hours per year, per batch of product, or per square foot of physical plant. For example, we assumed that time spent on the sanitation of physical plants is a function of the square footage. We assumed 1 hour per week for very small establishments, 3 hours per week for small establishments, and 20 hours per week for large establishments. We request comment or data about costs, hours, and the other requirements for these proposed required procedures.

vii. *Other costs.* The main costs in this category are for pest and rodent control. We consulted a commercial supplier of these services for the estimated monthly costs, which were $400 to $600 a month for very small establishments, $480 to $720 for small establishments, and $700 to $1,000 for large establishments (Ref. E52). For each size of establishment, we selected the midpoint of the range as the most likely value.

d. *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 would incur a cost. To get an estimate of the average cost of provision (adjusted for baseline activities) for each category, we multiplied the average cost per establishment by the probability that the establishment would need to undertake the expense (one minus the probability that the establishment was already doing it). For each provision of the proposed rule, the simulation carried out the following calculation:

Cost per unit of analysis for each provision = number of units of analysis per establishment × probability that establishment incurs cost × adjustment for requirement (yes or no) = cost per provision per establishment

We estimated both a setup cost (a one-time fixed cost) of the provision and an annual recurring cost. The first-year costs would be the setup costs plus the annual costs. To get the total costs of the rule, we multiplied the number of establishments in each size category (from the survey) by the average costs per establishment in that category. We then adjusted 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 estimated that 1,566 firms are in the industry. We estimated costs with the following calculation:

[Number of very small establishments × costs per very small establishment) + (Number of small establishments × costs per small establishment) + (number of large establishments × costs per large establishment)] × adjustment for establishments not in survey

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 15 of this document are used in the cost estimates, and are generated from multiple sources.

TABLE 15.—VALUES USED IN COST CALCULATIONS

| Name | Value or distribution used | Source |
|---|---|---|
| Average wage per hour | $15.65 | Employment Index, Bureau of Labor Statistics. |
| 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. |
| Average annual number of batches | Very small = 223; small = 554; large = 309 | Ref. E44. |

TABLE 15.—VALUES USED IN COST CALCULATIONS—Continued

| Name | Value or distribution used | Source |
|---|---|---|
| Annual time recordkeeping | 1/10 of setup time per provision | Ref. E44. |
| Personnel sanitation | 1 hour per week per worker | Assumption, based on requirements of proposed rule. |
| Sanitation time for physical plant | 1 hour per week for very small establishments; 3 hours per week for small establishments; 20 hours for physical plant per week for large establishments. | Assumption, based on difference in average physical plant size. |
| Sanitation supervisor | Very small and small establishments = 1 hour per week; large establishments = 1 hour per week. | Assumption, based on number of workers. |
| 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. E52. |
| 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. E52. |
| 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. |
| Minimum quality control unit | 1 person or 1 percent of establishment work force. | Assumption based on requirements of proposed rule. |
| Equipment replacement | For very small establishments, 0 to $1,000, with $100 most likely; small, 0 to $10,000, with $1,000 most likely; large, 0 to $100,000 with $1,000 most likely. | Assumption, based on size of establishments. |
| Setup costs for automatic equipment | $500 for hardware, 16 hours | Software costs and assumptions about labor hours. |
| Annual costs for automatic equipment | 1 to 2 hours per month for very small and small establishments; 2 to 4 hours per month for large establishments. | Assumption based on average size of establishments. |
| Sanitation of equipment and surfaces | 5 hours per week for very small establishments, 15 hours per week for small establishments, 100 hours per week for large establishments. | Assumption based on average sizes of establishments. |
| Number of dietary ingredients per batch, supplements other than vitamins. | 12.8; standard deviation = 15.6 | Ref. E46. |
| Number of dietary ingredients per batch, supplements other than vitamins. | 3.6; standard deviation = 4.8 | Ref. E46. |
| Cost per test | $20 to $150, with $50 most likely | See text discussion. |
| Holding products and dietary ingredients: capital requirements. | Setup cost for very small 0 to $1,000, with $100 most likely. Multiply by 3 for small establishments and by 20 for large establishments. | Based on average sizes of establishments. |
| Default probabilities that establishments are not currently acting in accordance with a provision. | For very small establishments, 0.2; for small establishments, 0.1, for large establishments, 0.01. | Based on results of survey for other practices. |

We combined the costs per establishment with the number of establishments and probabilities from the survey, and adjusted for establishments not in the survey to estimate the total costs of the proposed rule. Table 16 of this document summarizes the estimated total costs for very small establishments, small establishments, large establishments, and warehouses. Table 17 of this document shows the total costs for the first year and annually after the first year, assuming that the proposed rule is phased in over 3 years. Table 18 of this document shows the total costs of the proposed rule compared to the total costs of other options.

TABLE 16.—SUMMARY OF COSTS BY SIZE OF ESTABLISHMENT

| | Number of establishments | 1st Year costs per establishments | Annual costs per establishments | Total 1st year costs (in millions) | Total annual costs (in millions) |
|---|---|---|---|---|---|
| Very small establishments | 740 | $62,000 | $38,000 | $46 | $28 |
| Small establishments | 766 | 99,000 | 61,000 | 76 | 47 |
| Large establishments | 60 | 83,000 | 47,000 | 5 | 3 |
| Warehouses and other holders | 26,617 | 436 | 342 | 12 | 9 |

TABLE 17.—ESTIMATED TOTAL COSTS

[In millions]

| | 1st Year | 2nd Year | 3rd Year | 4th Year and after |
|---|---|---|---|---|
| Very small establishments | 0 | 0 | $46 | $28 |
| Small establishments | 0 | $76 | 47 | 47 |
| Large establishments | 5 | 3 | 3 | 3 |
| Warehouses | 12 | 9 | 9 | 9 |
| Total | 17 | 88 | 105 | 87 |

8. Summary of Benefits and Costs

We estimated that, once it is fully implemented, the measured annual benefits from the proposed rule would be $218 million; measured annual costs would be about $86 million. Additional but unmeasured benefits should also be recognized when comparing the total costs and benefits. Table 18 of this document compares the benefits and costs of the proposed rule to the benefits and costs of the leading regulatory options. Because the phase in period, complicates the comparison for the early years, we limit the comparison to annual benefits once all establishments are covered.

TABLE 18.—ANNUAL BENFITS AND COSTS OF REGULATORY OPTIONS

[In millions]

| Regulatory option | Annual benefits | Annual costs |
|---|---|---|
| Proposed rule | $218 | $86 |
| Fewer requirements for vitamins and minerals | 109 | 69 |
| Stricter CGMP | 218 | 178 |
| HACCP only | 42 | 38 |
| Testing only (unable to estimate) | ..... | 32 |
| High risk products only (unable to estimate) | ..... | (1) |

[1] Less than $86 million.

*Uncertainties in the analysis.* In this section, we list all of the significant assumptions in the analysis, which if varied, could significantly change the estimates of costs and benefits. Such changes could have importance for the construction of any potential final rule. Therefore, we ask that comments address these aspects of the analysis and, where possible, provide FDA with better data to reduce the uncertainty. We estimated the benefits using indirect methods, which required several key assumptions that are critical for our estimates. With the exception of the recall benefit, which is based directly on FDA recall records, each component of the estimated benefits involves assumptions that reflect our uncertainty.

Our basic assumption is that manufacturers lack market-based incentives to prevent hidden product quality defects. Our survey (Ref. E2) indicated that many firms do not have reliable quality control mechanisms in place. The survey was a one-time look at the manufacturing practices during the time of the survey. If the trend in the market is toward the adoption of the controls that we are proposing here in the absence of regulation, then both the cost and benefits of the rule will be less than we estimate. If the market-based trend is toward fewer controls, then both the cost and benefits of the regulation will be greater. Other key assumptions are listed below:

The assumptions for the health benefits from reducing the number of sporadic illnesses model are:

1. The baseline health of consumers is normal, not perfect. To estimate the change in health status from consuming defective products, we assumed that the baseline health of consumers is normal, which does not mean that we assumed that consumers have perfect health. We recognize that consumers will already have ''background'' health problems, by which we mean that many will have health problems unrelated to the consumption of defective products. Our assumption is that only the change in health status is relevant for our analysis. If an immune-compromised consumer is made ill by a defective product, *e.g.*, gets lead poisoning, the consumer might in fact have more difficulty recovering than an otherwise healthy person. However, we assume that the change in productivity, functional state, pain and suffering, and medical costs will be the same, regardless of prior health status. Accounting for confounding factors would have the effect of making health problems worse than we estimate, not better, so our estimate may be understating the true health benefits.

2. The average value of a QALY is $630 per day. That value, $630 per day, is in turn based on: (1) The value of a statistical life of $5 million; (2) the expected remaining life of consumers of 21.84 years (average), discounted from 36 years; and, (3) the social rate of time preference of 3 percent. The estimate is derived from workers in somewhat risky occupations who demand a wage premium for their additional risk of fatality. If our estimate of the value of a statistical life of workers does not represent the value of a statistical life of consumers of dietary supplements, then our benefits estimate will be different from the true health benefits of the rule. If consumers value their life differently than workers or if consumers place different values for different kinds of hazard-related deaths than do workers for job-related safety hazards, then we will have incorrect estimates for the true health benefits. If we discount life expectancy by 7 percent instead of 3 percent, the benefits would be much higher.

3. There is one illness for each recall. We assumed that for each class 1 and 2 recalled product there was only one illness that was reported to the public health authority. For instance, if a product was recalled because the defective product contained lead, we assume that a person was made ill from lead poisoning and that was how the recalled product was discovered. If there were more illnesses per recall than one, then our estimates of benefits will be low. If fewer than one illness per recall occurred (or is likely to occur in the future), then our estimate of health benefits will be more than the actual health benefits.

4. The assumed frequency of actual illnesses is 100 times the frequency of reported illnesses. This assumption is based on Ref. E16. We recognize that the factor of 100, although it has empirical support, might be wrong and that there is likely to be considerable uncertainty about this point estimate. It is widely believed in the public health community that most illnesses are underreported to public health authorities, particularly in passive reporting systems, such as the case with

dietary supplements. Mild cases are the most underreported. For instance, victims rarely notify public health authorities when they have minor gastrointestinal tract related illnesses. It is even more rare to report the likely source of a mild illness. It is also widely believed that severe illnesses and death are reported much more frequently than milder illnesses, even when the cause of illness or death is not included in the report. Although the number of deaths that are reported probably approach 100 percent, the cause of death from a contaminated dietary supplement product might not be reported. We believe that using a single composite factor—100—to represent the total number of all unreported cases, including mild, severe, and death, does not invalidate our assumption. The factor of 100 represents an estimate of the composite probability of the full range of probabilities for each severity level of an illness being reported. Increasing the factor multiplier from 100 to some number higher would increase the health benefits, while lowering the multiplier would decrease the health benefits. If we assume that all illnesses are reported—there are no unreported illnesses and no factor of 100, then the health benefits from fewer sporadic illnesses will be less than $1 million.

5. Introducing CGMP's will reduce the probability of a recall to zero. We believe that the proposed CGMP's creates the most reliable means for discovering product adulteration. Indeed, we believe that it will, if strictly used, cause the discovery of all adulteration. Therefore, we assume that once an establishment fully adopts the requirements, there should be no more health risk from adulterated dietary supplements and consequently, no more class 1 and 2 recalls. This conclusion rests on the assumption that there will be 100 percent compliance with this regulation. We recognize that human error is inescapable. If recalls—or a health risk from adulteration—would still exist, then we overstated the true health benefits of the regulation.

The assumptions for the health benefits from lowering the likelihood of rare catastrophic event model are:

1. We assume that a rare catastrophic event would occur every 30 years. We recognize that the occurrence of a single event provides little evidence about what will happen in the future. If the event reported in this analysis was in fact a one-time occurrence, then our estimate of the benefits from the prevention of the catastrophic health event would overstate the true benefits, which in fact should be zero. There would have been no future event, and there would be no benefit from adopting a rule to avoid it. If a rare event would have happened more frequently than our estimate of once every 30 years, then our estimate of the benefits would underestimate the true health benefits.

2. Number of illnesses per rare event. We based our estimate of the health impact from contaminated L-Tryptophan. If the number of illnesses from a future rare event differed—either more or less—then the health benefits would differ from our estimated benefits. If a future event would have had 10,000 cases, not 1,500 cases, then our estimate would understate the true health benefits of avoiding such a large catastrophe.

The assumptions for fewer products recalled are:

1. The reported class 1 and 2 recalls that have occurred over the last 10 years represent the number and type of recalls that would have occurred in the future but for the implementation of this regulation. If the number or types of recalls are not representative, then we over or under estimated the benefit of avoiding recalls. Avoiding one very large recall could result in significantly higher benefits. Conversely, merely avoiding fewer or smaller recalls would result in smaller benefits.

2. A product recall causes sellers to lose both goodwill and the value of the recalled product and lost goodwill equals the value of the recalled product. These two embedded assumptions have empirical support from Ref. E24. A product recall adversely affects the wealth of sellers—a recall leads to lost goodwill—by signaling to consumers that products are defective. From evaluating the declines in public share prices after product recalls in various industries, the authors in Ref. E24 determined that the loss in share price is twice the value of the loss of the actual value of the product recalled. They attribute the difference to lost firm goodwill.

3. Full compliance with the proposed CGMP's will reduce the probability of a recall to zero. As in our earlier assumption about the probability of recalls after the rule is adopted, consistency requires that if we believe that the rule will reliably cause the discovery of adulterated products before they are commercially available, there should be no more health risk from adulterated dietary supplements. Consequently, there should be no more recalls.

We developed the hypothetical search model to estimate the implicit value to consumers of better product quality although we lacked a model that could enable us to directly estimate consumer preferences for dietary supplement quality. With the adoption of the proposed rule, the standardization of manufacturing practices will reduce product differentiation. In a perfect information market, the change in product differentiation would be reflected in the change in the price differences between low and high quality products. In the existing market, price differences alone are an inadequate signal because the differences in product quality are typically hidden from the view of both consumers and (though less so) manufacturers. In this hypothetical model, we assumed that if there were actually indicators of product quality in the market now, consumers would spend a certain amount of time attempting to find a reasonably high quality product. Time spent searching is an economic cost. In fact, in markets where quality is discernible prior to purchase, such search does take place and it is from those markets that our estimates were derived. In such a world of easily available product quality signals, this regulation, by standardizing product quality at the high end, would reduce that search time. Our assumption is that this is a reasonable indicator of consumers' value for high quality products. Further, we assume that in fact consumers of dietary supplements do wish to purchase high quality products, as the absence of quality could mean either an ineffective product or worse, illness or death. We used various assumptions at each step in our model, and the benefits change when the assumptions change. The assumptions that we used for the search model are:

1. Consumers will search until the expected benefits of the search equal the expected cost of additional search. The expected cost is the value of their time, which we estimated is the average wage rate for manufacturing workers—$15.65/hour. If the true wage rate is different, the benefits of the rule will be different.

2. The three models—drug store, use of time and grocery store models—represent consumers of dietary supplements. If not, then we will not have estimated the true preferences of consumers. If consumers value dietary supplements more highly than either drugs, groceries or other uses of time, and they search more for better quality, then we understated the benefits of product standardization. If consumers value dietary supplements less highly than either drugs, they search more for better quality, then we overstated the benefits.

3. The quality controls will reduce consumer search time by approximately

33 percent. If our estimate is not representative of the true average reduction, then our estimate will be wrong.

4. The type and number of consumers represent the true value. If children, the elderly or other consumers search for these products in significantly greater amounts than average workers or the estimated population, then we may have overstated the benefits, because their foregone wages would be less than that of average workers.

In an ideal analysis, the benefits and costs of each provision would be evaluated. We were not able to quantify the benefits for each of the provisions in our analysis although we do have fairly detailed estimates of the cost. We request comments on marginal costs and benefits of specific provisions in the rule. Comments can be directed either at how well a specific provision might work to make dietary supplements either safer or of higher quality, or be directed at the cost of the provision. An example of this type of provision follows for recordkeeping:

Benefits of Recordkeeping

Mandatory recordkeeping is intended to help the discovery of manufacturing practices that create defective products. Recordkeeping ensures that preventative controls are carried out for each batch of dietary supplements produced. Records serve as a checklist that quality control personnel can consult to monitor that necessary controls are implemented or corrective actions taken. Further, mandatory recordkeeping provides an incentive for manufacturers to comply more fully with the provisions of the rule where recordkeeping is required. Knowing that FDA inspectors will examine records and that falsifying them is a criminal offense provides strong incentives to keep thorough and accurate records that the required safety functions have been performed adequately and in a timely manner. Thus, the benefits of recordkeeping are to permit detection of defective products and increase compliance with the provisions for which recordkeeping is required. If, for example: (1) The total benefits of the requirements that have recordkeeping attached to them were $50 million (not the real value); (2) only half of the requirements would be met without recordkeeping; and, (3) recordkeeping raised the compliance rate to 100 percent, then the benefits of recordkeeping would be $25 million. We were not able to quantify the marginal benefits of this requirement with numbers like this. Comments are requested for how well records are likely to perform this function. We estimate that the additional cost to society for the proposed new recordkeeping requirement will be approximately 10 percent of the total annual cost of the proposed regulation, or a little less than $9 million per year.

Further, we request comments on all of the provisions that would be of a similar nature to this example.

The costs of the rule depend on our assumptions about the amount and cost of testing. The amount of testing is highly uncertain; we have tried to model the number of tests based on number of ingredients and types of tests.

We first characterized the uncertainty as a probability distribution. We ran 1,000 computer simulations to estimate both benefits and costs. The simulations used distributions and assumptions from tables 8 through 13 of this document in place of single estimates.

TABLE 19.—DISTRIBUTION OF SIMULATION RESULTS FOR ANNUAL BENEFITS AND COSTS

[In millions]

| | 5th Percentile | Median | Mean | 95th Percentile |
|---|---|---|---|---|
| Annual benefits | $89 | $198 | $218 | $405 |
| Annual costs | 62 | 80 | 86 | 128 |

The computer simulation gives the distribution of estimated benefits and costs. If the underlying distributions capture the uncertainty of the estimates, then the results in table 19 of this document give a clear picture of the uncertainty. Another way to show the uncertainty is to see how sensitive the results are to plausible changes in individual variables. We start with benefits.

TABLE 20.—SENSITIVITY OF BENEFITS

[In millions]

| Description | Estimated annual benefits |
|---|---|
| The proposed rule | $218 |
| If reporting rate of illness is 0.1 (baseline is 0.01) | 182 |
| If reporting rate of illness is 0.005 (baseline is 0.01) | 257 |
| If the value of a statistical life is $3 million (baseline is $5 million) | 175 |
| If the value of a statistical life is $7 million (baseline is $5 million) | 259 |
| If consumer search time per item is 1 minute (baseline is 3.75 minutes) | 137 |
| If consumer search time per item is 5 minutes (baseline is 3.75 minutes) | 250 |
| If consumer search time equals 40 percent of shopping time (baseline is 70 percent) | 166 |
| If consumer search time is equal to shopping time (baseline is 70 percent) | 254 |
| If consumer search for quality accounts for 30 percent of search time (baseline is 20 percent) | 278 |
| If consumer search time for quality accounts for 10 percent of search time (baseline is 20 percent) | 158 |
| If catastrophic events are not prevented (baseline is $66 million annual benefit from prevention) | 152 |

We mainly looked at the cost effects of changing assumptions about testing and consumer complaints. As table 21 of this document shows, annual costs are quite sensitive to the assumptions about the average cost and number of tests.

TABLE 21.—SENSITIVITY OF COSTS

[In millions]

| Description | Estimated Annual Costs |
|---|---|
| The proposed rule | $86 |
| 6 tests per batch (baseline is 3) | 119 |
| 1 test per batch (baseline is 3) | 66 |
| $100 per test (baseline is $60) | 101 |
| 1 consumer complaint per 20 batches (baseline is 1 per 10) | 77 |
| 1 consumer complaint per 5 batches (baseline is 1 per 10) | 104 |

*C. Initial Regulatory Flexibility Analysis*

1. Introduction

FDA has examined the economic implications of this proposed 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 proposed rule would 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 proposed regulations would affect many small entities. Our classification of establishment size is based on the Small Business Administration's definition for small, as discussed previously in this document. A small business by this definition is any establishment with fewer than 500 employees. For this analysis, we defined very small establishments as establishments with fewer than 20 employees. Some small and very small establishments produce very large revenues and would probably not incur a large decline in profitability from the proposed CGMP regulations. We lack precise information about those establishments. Based on the survey, we estimated that 830 establishments, 53 percent of the total establishments, could be classified as very small (under 20 employees) and 564 as small (20 to 499 employees), which is 36 percent of the total establishments.

We estimated that 95 percent of all holders (warehouses and wholesalers) covered by this regulation are small using the Small Business Administration definition. The total number of holders likely to be affected by this regulation is 26,617 (*see* table 4 of this document), so the total number of holders that are small would be 25,286 (= 0.95 × 26,617).

The small establishments that would be affected by the proposed regulations are those establishments that would have to perform the various required activities, and that would not have done so without the regulations. As in the preliminary regulatory impact analysis (section VII.B of this document), we determined our estimate of baseline (pre-CGMP) 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 proposed CGMP regulations now. Those that do not follow the proposed requirements will incur a cost to do so.

b. *Costs to small entities.* Implementation costs vary across establishments based on current practices and the types of products manufactured, packaged, or held. We estimated the range of current practices using the survey of the industry. The cost model divided establishments by size, which allowed us to estimate the distribution of costs per establishment for each size and product class. Table 22 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 the table shows, costs per establishment are proportionally higher for very small than for large establishments. The table's most striking result is that costs are highest for small (20 to 499 employees) establishments.

TABLE 22.—COST PER ESTABLISHMENT

| | 1st year | Annual |
|---|---|---|
| Very small—fewer than 20 employees; median revenue under $1 million | $62,000 | $38,000 |
| Small—20 to 499 employees; median revenue $5 to 10 million | 99,000 | 61,000 |
| Large—500 or more employees; median revenue $20 to $50 million | 83,000 | 47,000 |

Small establishments that do not perform a substantial number of the actions required by the proposed CGMP regulations would bear relatively high costs for compliance with the provisions of this proposed rule. As shown in table 22 of this document, we estimated the average annual compliance costs for a very small establishment to be around $38,000. About one-third of those establishments or about 500 firms have annual sales revenues under $500,000. In addition, the average annual compliance cost for a small establishment is around $61,000. As the survey indicated, about 14 percent of establishments with 20 to 499 employees or about 200 firms have annual sales revenues under $500,000. For purposes of our analysis, we regard firms with revenues of $500,000 or less to be low revenue firms. Although the proposed rule would raise product prices, the price increase (which would largely be determined by changes made by large establishments) would be much smaller than the increase in the average costs of very small producers. The average burden to very small low revenue firms, then, would be at least 8 percent of their annual revenue. The average burden to small low revenue firms would be at least 12 percent of annual revenue. Establishments with above average costs, and even establishments with average costs,

would be hard pressed to continue to operate. Therefore, some of these establishments, for example, such as those that produce other products (foods or pharmaceuticals) or are part of firms with more than one establishment, may decide it is too costly and either change product lines or go out of business. If we assume that one half of these firms have sales revenues from other products and locations and remove them from the at-risk group, we are left with approximately 350 very small and small establishments with less than $500,000 in revenue. It is possible that a large number of these 350 very small and small establishments would be unable to absorb the compliance costs and will close.

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 proposed rule. Most entities affected by this proposed rule, however, are small. Exempting small establishments from some or all of its provisions would be likely to reduce benefits.

b. *Longer compliance periods.* Lengthening the compliance period would provide regulatory relief for small entities. A longer compliance period for small entities would 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 would also delay the impact of the annual costs of compliance. We have given very small and small firms an additional 2 years for compliance. The proposed rule, then, would be phased-in over 3 years, with large firms complying after 1 year, and both very small and small firms after 3 years. After 3 years, the annual costs would be incurred. The cost savings of delay may well be larger than simply the present value of the delay because very small and small firms may also be able to reduce their compliance costs by taking advantage of increases in industry knowledge and experience in implementing CGMP regulations. A summary of the compliance costs is shown in table 22 of this document.

Although lengthening the compliance period would provide some regulatory relief to small entities, relief for these provisions would also delay the full realization of the benefits of the proposed rule.

4. Description of Recordkeeping and Reporting

The Regulatory Flexibility Act requires a description of the recordkeeping and recording required for compliance with this proposed rule. This proposed rule would require the preparation of records. As described in the Preliminary Regulatory Impact Analysis, records must be written or electronic documents must be kept that demonstrate that specific action or actions occurred in the manufacturing process in compliance with the proposed regulations. Records that would be required in this proposed rule would demonstrate, that corrective actions were taken, that equipment, instruments, and controls used in laboratory operations and quality control were installed properly, and calibrated; that maintenance programs were followed; and that the results of any testing meet the necessary 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 to perform 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 proposed CGMP regulations would have a significant economic impact on a substantial number of small entities.

*D. Unfunded Mandates*

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The current inflation-adjusted statutory threshold is $112 million. The proposed rule qualifies as a significant rule under the statute because there is a significant possibility that the cost of the rule will be above the threshold. Most of the requirements of the Unfunded Mandates are fulfilled in the Executive Order 12866 analysis. The requirements under the Unfunded Mandates 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.

Future Costs

The future costs from the rule include the recurring costs, which reach their long-term value in the third year after the proposed rule would become final. These costs would be incurred by the establishments that manufacture, process, pack, transport, distribute, receive, hold, or import dietary ingredients or dietary products. Recurring costs from the regulatory requirements would be incurred in each future year. Table 18 of this document summarizes the annual future recurring costs.

Particular Regions, Communities, or Industrial Sectors

The costs of the rule will be shared among manufacturers, processors, packagers, transporters, receivers, holders, and importers of dietary ingredients or dietary products as well as domestic consumers. The higher costs incurred by domestic suppliers of dietary supplement products as a result of these regulations will mostly be passed on to consumers in the form of higher prices. Since consumer demand for dietary supplements is price elastic, most of the higher costs incurred by suppliers will be passed on to consumers. Consequently, higher dietary supplement prices will reduce real incomes for many consumers. However, the reduction in real incomes is thought to be more than offset by the benefits from these regulations. These benefits are measured as an improved ability by the FDA to respond to and contain threats of serious adverse health consequences from accidental contamination of dietary supplements.

National Productivity, Economic Growth, Job Creation, and Full Employment

Although this proposed regulation is significant, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

Exports

This proposed rule would require additional controls to be kept throughout the production and distribution chain for the manufacture of dietary ingredients and dietary supplements. The additional control costs would increase the total costs of production and distribution for all of the regulated products, including products sold within the U.S. and across national borders. These increased costs will be largely 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 proposed rule the increases in the price of United States exports (and resulting decreases in quantity demanded) would be quite small.

## VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We consulted with seven State officials to make a tentative determination about whether this proposed rule would have federalism implications. Based on this consultation, it does not appear that this proposed rule has federalism implications. In addition, we sent a letter on March 7, 2000, to elected State officials and their representative organization to notify them that our unified agenda was published on November 22, 1999, and identified this proposed CGMP rule as a rule that would publish in the year 2000. In that letter, we solicited comments on any federalism implications that this proposed rule may have. To date, no responses have been received to our solicitation. After publishing this proposed rule, FDA will send a letter to elected State officials and their representative organization requesting consultation about any federalism implications. We invite comment on our tentative determination that this proposed rule does not have federalism implications, and therefore, does not contain policies that have substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government.

## IX. Request for Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any written comments, except that individuals may submit one hard 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

## X. References

We have placed the following references on display in the Dockets Management Branch (*see* **ADDRESSES**). You may see them between 9 a.m. and 4 p.m., Monday through Friday.

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**List of Subjects**

*21 CFR Part 111*

Dietary foods, Drugs, Foods, Packaging and containers.

*21 CFR Part 112*

Drugs, Packaging and containers, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR chapter I, parts 111 and 112 as set forth below:

## PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

1. The authority citation for part 111 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 348, 371, 374, 381, 393; 42 U.S.C. 264.

2. The part heading for part 111 is revised as set forth above.

3. Add new subpart A to part 111 to read as follows:

### Subpart A—General Provisions

Sec.
111.1 Who is subject to these regulations?
111.2 What are these regulations intended to accomplish?
111.3 What definitions apply to this part?
111.5 Do other statutory provisions and regulations apply?
111.6 Exclusions.

## Subpart A—General Provisions

### § 111.1 Who is subject to these regulations?

You are subject to the regulations in this part if you manufacture, package, or hold a dietary ingredient or dietary supplement.

### § 111.2 What are these regulations intended to accomplish?

The regulations in this part establish the minimum current good manufacturing practices that you must use to the extent that you manufacture, package, or hold a dietary ingredient or dietary supplement.

### § 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 these regulations. For the purpose of these regulations, 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 ingredient or dietary supplement.

*Batch* means a specific quantity of a dietary ingredient or dietary supplement that is intended to meet specifications for identity, purity, quality, strength,

and composition, and 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, or holding of a batch or lot of dietary ingredients or dietary supplements can be determined.

*Component* means any substance intended for use in the manufacture of a dietary ingredient or dietary supplement including those that may not appear in the finished dietary ingredient or dietary supplement. Component includes ingredients and dietary ingredients as described in section 201(ff) of the Act.

*Consumer complaint* means communication that contains any allegation, written or oral, expressing dissatisfaction with the quality of a dietary ingredient or 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 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.

*Contact surface* means any surface that contacts a component, dietary ingredient, dietary supplement, and those surfaces from which drainage onto the component, dietary ingredient, dietary supplement, or onto surfaces that contact the component, dietary ingredient, or dietary supplement ordinarily occurs during the normal course of operations. Examples of contact surfaces include, but are not limited to, containers, utensils, tables, contact surfaces of equipment, and packaging.

*Ingredient* means any substance that is used in the manufacture of a dietary ingredient or dietary supplement that is intended to be present in the finished dietary ingredient or dietary supplement. An ingredient includes, but is not necessarily limited to, a dietary ingredient as described in section 201(ff) of the Act.

*Inprocess 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 ingredient or dietary supplement.

*Lot* means a batch, or a specific identified portion of a batch intended to have uniform identity, purity, quality, strength, and composition; or, in the case of a dietary ingredient or dietary supplement produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is intended to have uniform identity, purity, quality, strength, and composition.

*Microorganisms* means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes, but is not limited to, species that:

(1) Have public health significance;

(2) Could cause a component, dietary ingredient, or dietary supplement to decompose;

(3) Indicate that the component, dietary ingredient, or dietary supplement is contaminated with filth; or

(4) Otherwise may cause the component, dietary ingredient, or dietary supplement to be adulterated.

*Must* is used to state mandatory requirements.

*Pest* means any objectionable insects or other animals including, but not limited to, birds, rodents, flies, mites, and larvae.

*Physical plant* means all or parts of a building or facility used for or in connection with manufacturing, packaging, or holding a dietary ingredient or dietary supplement.

*Quality control* means a planned and systematic operation or procedure for preventing a dietary ingredient or dietary supplement from being adulterated.

*Quality control unit* means any person or group that you designate to be responsible for quality control operations.

*Representative sample* means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.

*Reprocessing* means using, in the manufacture of a dietary ingredient or a dietary supplement, clean, unadulterated components, dietary ingredients, or dietary supplements that have been previously removed from manufacturing for reasons other than insanitary conditions and that have been made suitable for use in the manufacture of a dietary ingredient or dietary supplement.

*Sanitize* means to adequately treat equipment, containers, utensils, or any other dietary product contact surface by applying cumulative heat or chemicals on cleaned food contact surfaces 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.

*Theoretical yield* means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular dietary ingredient or 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, dietary ingredient, 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 United States Food and Drug Administration (FDA).

*You* means a person who manufactures, packages, or holds dietary ingredients or dietary supplements.

### § 111.5 Do other statutory provisions and regulations apply?

In addition to the regulations in this part, 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.

### § 111.6 Exclusions.

The regulations in this part do not apply to a person engaged solely in activities related to the harvesting, storage, or distribution of raw agricultural commodities that will be incorporated into a dietary ingredient or dietary supplement by other persons.

4. Add new subpart B to part 111 to read as follows:

## Subpart B—Personnel

Sec.

111.10 What microbial contamination and hygiene requirements apply?
111.12 What personnel qualification requirements apply?

111.13 What supervisor requirements apply?

## Subpart B—Personnel

### § 111.10 What microbial contamination and hygiene requirements apply?

(a) *Microbial contamination.* You must take measures to exclude from any operations any person who might be a source of microbial contamination of any material including components, dietary ingredients, dietary supplements, and contact surfaces used in the manufacture, packaging, or holding of a dietary ingredient or a dietary supplement. Such measures include, but are not limited to, the following:

(1) Excluding any person who, by medical examination or supervisory observation, is shown to have, or appears to have an illness, open lesion, or any other abnormal source of microbial contamination, which may be expected to result in microbial contamination of components, dietary ingredients, dietary supplements, or contact surfaces, from working in any operations until the condition is corrected; 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 contaminate any components, dietary ingredients, dietary supplements, or any contact surface.

(b) *Hygienic practices.* If you work in operations during which adulteration of the component, dietary ingredients, dietary supplement, or contact surface may occur, you must use hygienic practices to the extent necessary to protect against contamination of components, dietary ingredients, dietary supplements, or contact surfaces. These hygienic practices include, but are not limited to:

(1) Wearing outer garments in a manner that protects against the contamination of components, dietary ingredients, 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 ingredients, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods in which components, dietary ingredients, 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 ingredients, dietary supplements, or contact surfaces;

(5) Maintaining gloves used in handling components, dietary ingredients, 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 ingredients, or dietary supplements or any contact surfaces are exposed or where contact surfaces are washed;

(8) Not eating food, chewing gum, drinking beverages and using tobacco products in areas where components, dietary ingredients, 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 ingredients, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

### § 111.12 What personnel qualification requirements apply?

(a) You must have qualified employees to manufacture, package, or hold dietary ingredients or dietary supplements; and

(b) Each person engaged in manufacturing, packaging, or holding must have the training and experience to perform the person's duties.

### § 111.13 What supervisor requirements apply?

(a) You must assign qualified personnel to supervise the manufacturing, packaging, or holding of dietary ingredients and dietary supplements.

(b) You and the supervisors you use must be qualified by training and experience to supervise.

5. Add new subpart C to part 111 to read as follows:

## Subpart C—Physical Plant

Sec.

111.15 What sanitation requirements apply to your physical plant?
111.20 What design and construction requirements apply to your physical plant?

## Subpart C—Physical Plant

### § 111.15 What sanitation requirements apply to your physical plant?

(a) *Physical plant facilities.* (1) You must maintain your physical plant in a clean and sanitary condition; and

(2) You must keep your physical plant in repair sufficient to prevent components, dietary ingredients, dietary supplements, or contact surfaces from becoming contaminated.

(b) *Cleaning compounds, sanitizing agents, and pesticides.* (1) You must use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and safe and adequate under the conditions of use.

(2) You must not use or hold toxic materials in a physical plant in which contact surfaces, components, dietary ingredients, or dietary supplements are manufactured or exposed, unless those materials are necessary:

(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 toxic cleaning compounds, sanitizing agents, pesticides, and pesticide chemicals in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

(c) *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 ingredients, 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 ingredients, 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 ingredients, dietary supplements, or contact surfaces.

(d) *Water supply.* (1) You must 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:

(i) Manufacturing dietary ingredients or dietary supplements;

(ii) Making ice that comes in contact with components, dietary ingredients, dietary supplements, or contact surfaces;

(iii) Cleaning any surface; and

(iv) Employee bathrooms and hand-washing facilities.

(2) Water that contacts components, dietary ingredients, dietary supplements, or any contact surface must at a minimum comply with the National Primary Drinking Water regulations prescribed by the Environmental Protection Agency under 40 CFR part 141 and any state and local government requirements;

(3) You must have documentation or otherwise be able to show that water that contacts components, dietary ingredients, dietary supplements, or any contact surface meets the requirements in paragraph (d)(2) of this section.

(e) *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 ingredients, 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 ingredients or dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.

(f) *Sewage disposal.* You must dispose of sewage into an adequate sewage system or through other adequate means.

(g) *Bathrooms.* You must provide your employees with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not become a potential source of contamination to components, dietary ingredients, dietary supplements, or contact surfaces. You must:

(1) Keep the bathrooms in good repair at all times;

(2) Provide self-closing doors; and

(3) Provide 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 (such as double doors or positive airflow systems).

(h) *Hand-washing facilities.* You must provide hand-washing facilities that are adequate, convenient, and furnish running water at a suitable temperature. You must do this by providing:

(1) 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;

(2) Effective hand-cleaning and sanitizing preparations;

(3) Air driers, sanitary towel service, such as disposable paper towels, or other suitable drying devices;

(4) Devices or fixtures, such as water control valves, designed and constructed to protect against recontamination of clean, sanitized hands;

(5) Signs that are easy to understand and are posted throughout the physical plant that direct employees handling components, dietary ingredients, dietary supplements, or contact surfaces to wash and, where appropriate, to sanitize their hands before they start work, after each absence from their duty station, and when their hands may have become soiled or contaminated; and

(6) Trash bins that are constructed and maintained in a manner to protect against recontamination of hands and contamination of components, dietary ingredients, dietary supplements, or any contact surface.

(i) *Trash disposal.* You must convey, store, and dispose of trash to:

(1) Minimize the development of odor;

(2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;

(3) Protect against contamination of components, dietary ingredients, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant; and

(4) Control hazardous waste to prevent contamination of components, dietary ingredients, dietary supplements, and contact surfaces.

(j) *Sanitation supervisors.* You must assign one or more employees to supervise overall sanitation. These supervisors must be qualified by training and experience to develop and supervise sanitation procedures.

**§ 111.20 What design and construction requirements apply to your physical plant?**

Any physical plant you use in the manufacture, packaging, or holding of dietary ingredients or 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 materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mixups of components, dietary ingredients, and dietary supplements during manufacturing, packaging, or holding;

(c) Permit the use of proper precautions to reduce the potential for mixups or contamination of components, dietary ingredients, 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, dietary ingredients, and dietary supplements during the following operations:

(1) Receiving, identifying, holding, and withholding from use, components, dietary ingredients, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, or holding of dietary ingredients and dietary supplements;

(2) Separating, as necessary, components, dietary ingredients, dietary supplements, packaging, and labels that are to be used from components, dietary ingredients, 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, and holding of different product types including, but not limited to, different types of dietary ingredients, 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 dietary ingredients or dietary supplements.

(d) Be designed and constructed in a manner that prevents contamination of

components, dietary ingredients, dietary supplements, or contact surfaces. The design and construction must include, but not be limited to:

(1) Floors, walls, and ceilings that are of smooth and hard surfaces that can be adequately cleaned and kept clean and in good repair;

(2) Fixtures, ducts, and pipes that do not contaminate components, dietary ingredients, dietary supplements, or contact surfaces by dripping 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 ingredients, dietary supplements, or contact surfaces;

(4) Fans and other air-blowing 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;

(5) Equipment that controls temperature and humidity; and

(6) 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 ingredients, dietary supplements, or contact surfaces with clothing or personal contact.

(e) Provide adequate light in:

(1) All areas where components, dietary ingredients, 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 that is suspended over exposed components, dietary ingredients, or dietary supplements in any step of preparation, unless otherwise constructed in a manner that will protect against contamination of components, dietary ingredients, or dietary supplements in case of glass breakage.

(g) Provide protection by any effective means against contamination of components, dietary ingredients, and dietary supplements in bulk fermentation vessels, including consideration of:

(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.

6. Add new subpart D to part 111 to read as follows:

**Subpart D—Equipment and Utensils**

Sec.
111.25 What requirements apply to the equipment and utensils you use?
111.30 What requirements apply to automatic, mechanical, or electronic equipment?

## Subpart D—Equipment and Utensils

### § 111.25 What requirements apply to the equipment and utensils you use?

(a)(1) 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. Equipment and utensils include, but are not limited to, 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 automatic, 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, dietary ingredients, 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, dietary ingredients, or dietary supplements;

(iii) Made of nontoxic materials;

(iv) Designed and constructed to withstand the environment of their intended use, the action of components, dietary ingredients, or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and

(v) Maintained to protect components, dietary ingredients, 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 component, dietary ingredient, or dietary supplement particles, dirt, filth, organic material, or any other extraneous materials or contaminants to minimize the opportunity for growth of microorganisms.

(5) Each freezer and cold storage compartment you use to hold components, dietary ingredients, or dietary supplements:

(i) Must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that shows the temperature accurately within the compartment; and

(ii) Must have an automatic device for regulating temperature or an automatic alarm system to indicate a significant temperature change in a manual operation.

(6) Instruments or controls used in the manufacturing, packaging, or holding of a dietary ingredient or dietary supplement, including but not limited to, instruments or controls you use to measure, regulate, or record temperatures, hydrogen ion concentration (pH), water activity, or other conditions that 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 ingredient, 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 ingredient, dietary supplement, or contact surface is not contaminated.

(b)(1) You must calibrate instruments and controls you use in manufacturing or testing a component, dietary ingredient, or dietary supplement.

(2) You must calibrate before first use; and

(i) As specified in writing by the manufacturer of the instrument and control, or

(ii) At routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument and control.

(c) You must:

(1) Establish a written procedure for calibrating instruments and controls you use in manufacturing or testing a

component, dietary ingredient, or dietary supplement and document that the written procedure was followed each time a calibration is performed, or

(2) Document at the time of performance that the instrument and control calibration established in accordance with this section was performed.

(d) You must identify the following for calibrating instruments and controls in any written procedure or at the time of performance:

(1) The instrument or control calibrated;

(2) The date of calibration;

(3) The reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy;

(4) The calibration method used including appropriate limits for accuracy and precision of instruments and controls when calibrating;

(5) The calibration reading or readings found; and

(6) The recalibration method used if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and

(7) The initials of the person who performed the calibration.

(d) You must repair or replace instruments or controls that cannot be adjusted to agree with the reference standard.

(e)(1) You must maintain, clean, and sanitize as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, or hold components, dietary ingredients, or dietary supplements. 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 of low-moisture components, dietary ingredients, or dietary supplements are in a dry and sanitary condition at the time of 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, dietary ingredients, 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 back-to-back operations involving different batches of the same dietary ingredient or dietary supplement, you must clean and sanitize the contact surfaces as necessary.

(4) You must clean surfaces that do not touch components, dietary ingredients, or dietary supplements as frequently as necessary to protect against contaminating components, dietary ingredients, 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 ingredients, dietary supplements, or any contact surface.

(6) Cleaning compounds and sanitizing agents must be adequate for intended use and safe under condition 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.

(f) You must keep calibration records as required by this section in accordance with § 111.125.

**§ 111.30 What requirements apply to automatic, mechanical, or electronic equipment?**

(a) When you use automatic, mechanical, or electronic equipment to manufacture, package, label, and hold a dietary ingredient or dietary supplement, you must:

(1) Design or select equipment to ensure that dietary ingredient or dietary supplement specifications are consistently achieved and

(2) Determine the suitability of your equipment by ensuring that your equipment is capable of operating satisfactorily within the operating limits required by the process.

(b) For any automatic, mechanical, or electronic equipment you use, you must:

(1) Routinely calibrate, inspect, or check to ensure proper performance. Your quality control unit must approve these calibrations, inspections, or checks;

(2) Make and keep written records of equipment calibrations, inspections, or checks;

(3) 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;

(4) Establish and use appropriate controls to ensure that the equipment functions in accordance with its intended use. These controls must be approved by your quality control unit; and

(5) Make and keep backup file(s) of software programs and of data entered into your computer system. 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. You must keep your backup software programs and data secure from alterations, inadvertent erasures, or loss.

(c) You must keep automatic, mechanical, or electronic equipment records required by this section in accordance with § 111.125.

**§ 111.50 [Redesignated as § 111.72 and Amended]**

7. Redesignate § 111.50 as § 111.72 and transfer it to a new subpart E, *Production and Process Controls,* and revise the section heading to read as follows:

**§ 111.72 What requirements apply to packaging of iron-containing dietary supplements?**

* * * * *

8. Add §§ 111.35 through 111.70 and § 111.74 to newly added subpart E to read as follows:

**§ 111.35 What production and process controls must you use?**

(a) You must implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary ingredients and dietary supplements.

(b) Your production and in-process control system must be designed to ensure that the dietary ingredient or dietary supplement is manufactured, packaged, and held in a manner that will prevent adulteration of the dietary ingredient or dietary supplement. The production and in-process control system must include all requirements of this subpart and must be reviewed and approved by the quality control unit.

(c) You must use a quality control unit in your manufacturing, packaging, and label operations for producing the dietary ingredient or dietary supplement to ensure that these operations are performed in a manner that prevents adulteration and ensures that the dietary ingredient or dietary supplement meets specifications for identity, purity, quality, strength, and composition.

(d) Any substance, other than a ''dietary ingredient'' within the meaning of section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act), 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 the dietary ingredient or dietary supplement must 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) of this chapter; or

(3) If used as a color additive, subject to a listing that, by the terms of that listing, includes the use in a dietary supplement; or

(4) Generally recognized as safe (GRAS) for use in a dietary ingredient or dietary supplement. Any claim that a substance is GRAS, other than a dietary ingredient within the meaning of section 201(ff) of the Act, 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 ingredient or dietary supplement; and

(5) Must comply with all other applicable statutory and regulatory requirements under the Act.

(e) You must establish a specification for any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration. Specifications must be established for:

(1) The identity, purity, quality, strength, and composition of components, dietary ingredients, or dietary supplements that you receive;

(2) The in-process controls in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;

(3) The identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement that you manufacture; and

(4) The dietary ingredient or dietary supplement labels and the packaging that may come in contact with dietary ingredients and dietary supplements. The packaging must be safe and suitable for its intended use and comply with all other applicable statutory and regulatory requirements under the Act and must not be reactive or absorptive so as to affect the safety of the dietary ingredient and dietary supplement.

(f) You must monitor the in-process control points, steps, or stages to ensure that specifications established under paragraph (e) of this section are met and to detect any unanticipated occurrence that may result in adulteration;

(g) You must ensure, through testing or examination, that each specification that you established under paragraph (e) of this section is met. Specific testing requirements are as follows:

(1) You must test each finished batch of the dietary ingredient or dietary supplement produced before releasing for distribution to determine whether established specifications for identity, purity, quality, strength, and composition are met, provided that there are scientifically valid analytical methods available to conduct such testing.

(2) For any specification for identity, purity, quality, strength, or composition for which you document cannot be tested on the finished batch of a dietary ingredient or dietary supplement, because there is no scientifically valid analytical method available for such testing, then you must:

(i) Perform testing on each shipment lot of components, dietary ingredients or dietary supplements received to determine whether such specification is met; and

(ii) Perform testing in-process in accordance with the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements; and

(3) Your quality control unit must determine when finished batch testing cannot be completed for any specification on the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements.

(h) You must use an appropriate test or examination to determine whether your specifications are met. An appropriate test is one that is a scientifically valid analytical method.

(i) You must:

(1) Establish corrective action plans for use when an established specification is not met;

(2) Review the results of the monitoring required by this section and conduct a material review of any component, dietary ingredient, dietary supplement, packaging or label for which you establish a specification that is not met, or any unanticipated occurrence that adulterates or could result in adulteration of the component, dietary ingredient, dietary supplement, packaging, or label; and

(3) Make a material disposition decision for any component, dietary ingredient, dietary supplement, packaging, or label:

(i) If a component, dietary ingredient, dietary supplement, packaging, or label fails to meet specifications;

(ii) If any step established in the master manufacturing record is not completed;

(iii) If there is any unanticipated occurrence during the manufacturing operations that adulterates or may lead to adulteration of the component, dietary ingredient, dietary supplement, packaging, or label;

(iv) If calibration of an instrument or control suggests a problem that may have caused batches of a dietary ingredient or dietary supplement to become adulterated; or

(v) If a dietary ingredient or dietary supplement is returned.

(4) For any deviation or unanticipated occurrence which resulted in or could lead to adulteration of the component, dietary ingredient, dietary supplement, packaging, or label:

(i) You must 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;

(ii) You must not reprocess a rejected component, dietary ingredient, or dietary supplement unless approved by the quality control unit; and

(iii) You must not reprocess any component, dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms or other contaminants, such as heavy metals;

(5) Have your quality control unit review and approve any material review and disposition decision described in paragraphs (i)(2) and (i)(3) of this section.

(j) 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 paragraph (i) of this section. The documentation must be included in the appropriate batch production record and must:

(1) Identify the specific deviation from the specification or the unanticipated occurrence;

(2) Describe your investigation into the cause of the deviation from the specification or the unanticipated occurrence;

(3) Evaluate whether or not the deviation from the specification or unanticipated occurrence has resulted in or could lead to adulteration;

(4) Identify the action(s) taken to correct and prevent a recurrence of the deviation or the unanticipated occurrence; and

(5) Discuss what you did with the component, dietary ingredient, dietary supplement, packaging, or label.

(k) You must test or examine components, dietary ingredients, and dietary supplements for those types of contamination that may adulterate or may lead to adulteration. You must use an appropriate scientifically valid method for the test or examination. The types of contamination include, but are not limited to, the following:

(1) Filth, insects, or other extraneous material;

(2) Microorganisms; and

(3) Toxic substances.

(l) Tests in accordance with this section must include at least one of the following:

(1) Gross organoleptic analysis;

(2) Microscopic analysis;

(3) Chemical analysis; or

(4) Other appropriate test.

(m) You must record results of all testing and examinations performed in accordance with this section. If a test or examination is performed on a batch production you must record the test or examination result in the batch production record in accordance with § 111.50(c)(10). Your records must document whether the testing and examination demonstrates that specifications are met.

(n) For any specification that is not met, you must conduct a material review and disposition decision under paragraph (i) of this section.

(o) You must make and retain records, in accordance with § 111.125, to ensure that you follow the requirements of this section. The records must include, but are not limited to:

(1) The specifications established;

(2) The actual results obtained during the monitoring operation;

(3) Any deviation from specifications and any unanticipated occurrences;

(4) Any corrective actions taken;

(5) The disposition decisions and followup; and

(6) The identity of the individual qualified by training and experience who investigated any deviation from specifications or unanticipated occurrence and the identity of the individual from the quality control unit who reviewed the results of that investigation.

**§ 111.37 What requirements apply to quality control?**

(a) You must use a quality control unit to ensure that your manufacturing, packaging, label, and holding operations in the production of dietary ingredients and dietary supplements are performed in a manner that prevents adulteration and misbranding, including ensuring that dietary ingredients and dietary supplements meet specifications for identity, purity, quality, strength, and composition.

(b) Your quality control unit must do the following:

(1) Approve or reject all processes, specifications, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, quality, strength, and composition of a dietary ingredient or dietary supplement;

(2) Determine whether all components, dietary ingredients, dietary supplements, packaging, and labels conform to specifications;

(3) Approve or reject all components, dietary ingredients, dietary supplements, packaging, and labels;

(4) Review and approve all master manufacturing records and all modifications to the master manufacturing records;

(5) Review and approve all batch production-related records which include, but are not limited to, cross referencing receiving and batch production records, approval of a material review and disposition decision, approval for reprocessing, and approval for releasing for distribution;

(6) Review and approve all processes for calibrating instruments or controls;

(7) Review all records for calibration of instruments, apparatus, gauges, and recording devices;

(8) Review all records for equipment calibrations, inspections, and checks;

(9) Review and approve all laboratory control processes, and testing results;

(10) Review and approve all packaging and label records which include, but are not limited to, cross-referencing receiving and batch production records, approval for repackaging and relabeling, and approval for releasing for distribution;

(11) Collect representative samples of:

(i) Each shipment lot of components, dietary ingredients, dietary supplements, packaging, and labels received to determine whether the component, dietary ingredient, dietary supplement, packaging, or labels meet specifications;

(ii) Inprocess materials 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, quality, strength, and composition of dietary ingredients or dietary supplements;

(iii) Each batch of dietary ingredient or dietary supplement manufactured to determine, before releasing for distribution, whether the dietary ingredient or dietary supplement meets its specifications for identity, purity, quality, strength, and composition; and

(iv) Each batch of packaged and labeled dietary ingredients or 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.

(12) 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 ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition. The reserve samples must:

(i) Be identified with the batch or lot number; and

(ii) Consist of at least twice the quantity necessary for tests.

(13) Perform appropriate tests and examinations of:

(i) Components, dietary ingredients, dietary supplements, packaging, and labels received to ensure that they meet specifications;

(ii) Dietary ingredient and dietary supplement batch production at points, steps, or stages identified in the master manufacturing record where control is necessary to prevent adulteration;

(iii) Dietary ingredients and dietary supplements that you manufacture to ensure that they meet specifications; and

(iv) Packaged and labeled dietary ingredients and dietary supplements to ensure that you used the packaging specified in the master manufacturing record and you applied the label specified in the master manufacturing record.

(14) Review and approve all material review and disposition decisions; and

(15) Approve the reprocessing or distribution of returned dietary ingredients or dietary supplements.

(c) Your quality control unit must establish and maintain written documentation at the time of performance that it performed the review, approval, or rejection requirements of this section by recording the following:

(1) Date the required review, approval, or rejection was performed; and

(2) Signature of the person performing the requirement.

(d) You must keep quality control records in accordance with § 111.125.

**§ 111.40 What requirements apply to components, dietary ingredients, dietary supplements, packaging, and labels you receive?**

(a) For components, dietary ingredients, or dietary supplements you receive, you must:

(1) 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, dietary ingredients, or dietary supplement;

(2) Visually examine the suppliers invoice, guarantee, or certification to ensure that the components, dietary ingredients, or dietary supplements are consistent with your purchase order and perform testing, as needed, to determine whether specifications are met.

(3) Quarantine components, dietary ingredients, or dietary supplements until your quality control unit reviews the suppliers invoice, guarantee, or certification and performs testing, as needed, of a representative sample to determine that specifications are met. If specifications are not met, you must conduct a material review and make a disposition decision. Your quality control unit must approve and release the components, dietary ingredients, and dietary supplements from quarantine before you use them;

(4) Identify each lot of components, dietary ingredients, or 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 component or dietary supplement, and the status (*e.g.,* quarantined, approved, or rejected) and to trace the shipment lot to the dietary ingredient or dietary supplement manufactured and distributed. You must use this unique identifier whenever you record the disposition of each shipment lot received; and

(5) Hold components, dietary ingredients, or dietary supplements under conditions that will protect against contamination, deterioration, and avoid mixups.

(b) For packaging and labels you receive, you must:

(1) 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 packaging and labels;

(2) Quarantine packaging and labels until your quality control unit tests or examines a representative sample to determine that specifications are met. You must conduct at least a visual identification on the containers and closures. If specifications are not met, you must conduct a material review and make a disposition decision. Your quality control unit must approve and release packaging and labels from quarantine before you use them;

(3) 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 ingredient or dietary supplement manufactured and distributed. You must use this unique identifier whenever you record the disposition of each shipment lot received; and

(4) Hold packaging and labels under conditions that will protect against contamination, deterioration, and avoid mixups.

(c)(1) The person who performs the component, dietary ingredient, dietary supplement, packaging, or label requirements of this section must document, at the time of performance, that the requirements were followed. The documentation must include, but not be limited to:

(i) The date that the components, dietary ingredients, dietary supplements, packaging, or labels were received;

(ii) The signature of the person performing the requirement;

(iii) Any test results; and

(iv) Any material review and disposition decision you conducted in accordance with § 111.35(i) and disposition of any rejected material under § 111.74.

(2) You must keep component, dietary supplement, packaging, and label receiving records in accordance with § 111.125.

**§ 111.45 What requirements apply to establishing a master manufacturing record?**

(a) You must prepare and follow a written master manufacturing record for each type of dietary ingredient or dietary supplement that you manufacture and for each batch size to ensure uniformity from batch to batch. The master manufacturing record must:

(1) Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration; and

(2) Establish controls and procedures to ensure that each batch of dietary ingredient or dietary supplement manufactured meets those specifications.

(b) The master manufacturing record must include the following information:

(1) The name of the dietary ingredient or dietary supplement to be manufactured and the strength, concentration, weight, or measure of each dietary ingredient for each batch size;

(2) A complete list of components to be used;

(3) An accurate statement of the weight or measure of each component to be used;

(4) 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 in compliance with section 403(s) of the Federal Food, Drug, and Cosmetic Act;

(5) A statement that explains any intentional excess amount of a dietary ingredient;

(6) A statement of theoretical yield of a manufactured dietary ingredient or dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to prevent adulteration, and the expected yield when you finish manufacturing the dietary ingredient or dietary supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is performed and material review is conducted and disposition decision is made;

(7) A description of packaging and a copy of the label to be used; and

(8) Written instructions including, but not limited to, the following:

(i) Specifications for each point, step, or stage in manufacturing the dietary ingredient or dietary supplement necessary to prevent adulteration;

(ii) Sampling and testing procedures;

(iii) Specific actions necessary to perform and verify points, steps, or stages, necessary to meet specifications and otherwise prevent adulteration, including, but not limited to, one person weighing or measuring a component and another person verifying the weight or measure and one person adding the component and another person verifying the addition;

(iv) Special notations and precautions to be followed; and

(v) Corrective action plans for use when a specification is not met.

(c) You must have the quality control unit review and approve each master manufacturing record and any modifications to a master manufacturing record.

(d) You must keep master manufacturing records in accordance with § 111.125.

**§ 111.50 What requirements apply to establishing a batch production record?**

(a) You must prepare a batch production record every time you

manufacture a batch of a dietary ingredient or dietary supplement and the batch production record must include complete information relating to the production and control of each batch.

(b) Your batch production record must accurately follow the appropriate master manufacturing record and you must perform each step in producing the batch.

(c) The batch production record must include, but is not limited to, the following information:

(1) The batch, lot, or control number;

(2) Documentation at the time of performance, showing the date on which each step of the master manufacturing record was performed, and the initials of the persons performing each step, including but not limited to:

(i) The person responsible for weighing or measuring each component used in the batch; and

(ii) The person responsible for adding the component to the batch.

(3) The identity of equipment and processing lines used in producing the batch;

(4) The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch;

(5) The shipment lot unique identifier of each component, dietary ingredient, dietary supplement, packaging, and label used;

(6) The identity and weight or measure of each component used;

(7) The initials at the time of performance or at the completion of the batch of the person responsible for verifying the weight or measure of each component used in the batch;

(8) The initials at the time of performance or at the completion of the batch of the person responsible for verifying the addition of components to the batch;

(9) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(10) The actual test results for any testing performed during the batch production;

(11) Documentation that the dietary ingredient and dietary supplement meets specifications;

(12) 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;

(13) Any documented material review and disposition decision in accordance with § 111.35(j); and

(14) Signature of the quality control unit to document batch production record review and any approval for reprocessing or repackaging.

(d) The quality control unit must review in accordance with § 111.37(b)(5) the batch production record established in paragraph (c) of this section.

(1) 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.

(2) The quality control unit must not approve and release for distribution any batch of dietary ingredient or dietary supplement that does not meet all specifications.

(e) The quality control unit must document in accordance with § 111.37(c) the review performed in accordance with paragraph (d) of this section and it must be documented at the time of performance. The review and documentation must include, but is not limited to, the following:

(1) Review of component, dietary ingredient, and dietary supplement receiving records including review of testing and examination results;

(2) 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;

(3) Records of investigations, conclusions, and corrective actions performed in accordance with paragraph (d) of this section; and

(4) The identity of the person qualified by training and experience who performed the investigation in accordance with paragraph (d) of this section.

(f) You must not reprocess a batch that deviates from the master manufacturing record unless approved by the quality control unit. You must not reprocess a dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms of public health significance or other contaminants, such as heavy metals;

(g) Any batch of dietary ingredient or dietary supplement that is reprocessed must meet all specifications for the batch of dietary ingredient or dietary supplement and be evaluated and approved by the quality control unit before releasing for distribution. The results of the reevaluation by the quality control unit must be documented in the batch production record;

(h) You must collect representative reserve samples of each batch of dietary ingredient or dietary supplement and 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 whether, for example, the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition; and

(i) You must keep batch production records in accordance with § 111.125.

**§ 111.60 What requirements apply to laboratory operations?**

(a) You must use adequate laboratory facilities to perform whatever testing and examinations are necessary to determine that components, dietary ingredients, and dietary supplements received meet specifications; that specifications are met during in-process, as specified in the master manufacturing record; and that dietary ingredients and dietary supplements manufactured meet specifications.

(b)(1) You must establish and follow laboratory control processes that are approved by the quality control unit. Laboratory control processes must include, but are not limited to, the following:

(i) Use of criteria for selecting appropriate examination and testing methods;

(ii) Use of criteria for establishing appropriate specifications; and

(iii) Use of sampling plans for obtaining representative samples of:

(A) Components, dietary ingredients, and dietary supplements received to determine whether specifications are met;

(B) In-process materials during the batch manufacturing when testing or examination is required in the master manufacturing record;

(C) Each batch of dietary ingredient or dietary supplement manufactured to determine that the dietary ingredient or dietary supplement meets specifications;

(D) Packaging and labels received to determine that the materials meet specifications; and

(E) Each batch of packaged and labeled dietary ingredients or dietary supplements to ensure that the label specified in the master manufacturing record has been applied.

(iv) Use of criteria for selecting standard reference materials used in performing tests and examinations;

(v) Use of appropriate test method validations; and

(vi) Use of test methods and examinations in accordance with established criteria.

(2) The person who conducts the testing and examination at the time of

performance, must document that laboratory methodology established in accordance with this section is followed. The documentation must include the testing and examination results.

(3) You must keep laboratory examination and testing records in accordance with § 111.125.

(c) You must verify that the laboratory examination and testing methodologies are appropriate for their intended use.

(d) You must identify and use the appropriate validated testing method for each established specification for which testing is required to determine whether the specification is met.

**§ 111.65 What requirements apply to manufacturing operations?**

(a) You must design or select manufacturing processes to ensure that dietary ingredient or dietary supplement specifications are consistently achieved.

(b) You must conduct all manufacturing operations in accordance with adequate sanitation principles.

(c) You must take all the necessary precautions during the manufacture of a dietary ingredient or dietary supplement to prevent contamination of components, dietary ingredients, or dietary supplements. These precautions include, but are not limited to:

(1) Performing manufacturing operations under conditions and controls that protect against the potential for growth of microorganisms and the potential for contamination;

(2) Washing or cleaning components that contain soil or other contaminants;

(3) Using water that meets the National Primary Drinking Water regulations or, where necessary, higher sanitary quality and that complies with all applicable Federal, State, and local regulations for water that is used in the manufacturing operation. If you reuse water that was used to wash components to remove soil or contaminants, the reused water must be safe and of adequate sanitary quality so that it does not become a source of contamination;

(4) Performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated components, dietary ingredients, and dietary supplements;

(5) 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;

(6) Holding components, dietary ingredients, and dietary supplements that can support the rapid growth of microorganisms of public health significance in a manner that prevents the components, dietary ingredients, and dietary supplements from becoming adulterated;

(7) Identifying and holding any components, dietary ingredients, or dietary supplements, for which a material review and disposition decision is required, in a manner that protects the components, dietary ingredients, or dietary supplements against contamination and mixups;

(8) Performing mechanical manufacturing steps (such as cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) by any effective means to protect the dietary ingredients or dietary supplements against contamination. Such steps must include consideration of:

(i) Cleaning and sanitizing contact surfaces;

(ii) Using temperature controls; and

(iii) Using time controls.

(9) Using effective measures to protect against the inclusion of metal or other foreign material in components, dietary ingredients, or dietary supplements. Compliance with this requirement must include consideration of the use of:

(i) Filters or strainers;

(ii) Traps;

(iii) Magnets; or

(iv) Electronic metal detectors.

(10) Segregating and identifying all containers for a specific batch of dietary ingredients or dietary supplements to identify their contents and, where necessary, the phase of manufacturing; and

(11) Identifying all processing lines and major equipment used during manufacturing to indicate their contents including the name of the dietary ingredient or dietary supplement and the specific batch or lot number and, when necessary, the phase of manufacturing.

(d) You must conduct a material review and make a disposition decision in accordance with § 111.35(i) for any component, dietary ingredient, or dietary supplement that fails to meet specifications or that is or may be adulterated. If the material review and disposition decision allows you to reprocess the component, dietary ingredient, or dietary supplement, you must retest or reexamine the component, dietary ingredient, or dietary supplement to ensure that it meets specifications and is approved by the quality control unit.

**§ 111.70 What requirements apply to packaging and label operations?**

(a) You must 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 ingredients or dietary supplements nor cause them to deteriorate;

(b) You must fill, assemble, package, and perform other related operations in a way that protects your dietary ingredients or dietary supplements against adulteration and misbranding. You must do this using any effective means, including but not limited to, the following:

(1) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary ingredient or dietary supplement containers, as appropriate;

(2) Protecting manufactured dietary ingredients and dietary supplements from contamination, particularly airborne contamination;

(3) Using sanitary handling procedures;

(4) Establishing physical or spatial separation of packaging and labels from operations on other dietary ingredients and dietary supplements to prevent mixups;

(5) Identifying, by any effective means, filled dietary ingredient or dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups;

(6) Identifying the dietary ingredient or dietary supplement with a batch, lot, or control number that can be used to determine the manufacturing history and control of the batch;

(7) Examining a representative sample of each batch of the packaged and labeled dietary ingredient or dietary supplement to ensure that the dietary ingredient or dietary supplement meets specifications and that the label specified in the master manufacturing record has been applied; and

(8) Suitably disposing of labels and other packaging for dietary ingredients or dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

(c) You must conduct a material review and make a disposition decision of any packaged and labeled dietary ingredients or dietary supplements that do not meet specifications.

(d) You must only repackage or relabel dietary ingredients or dietary supplements after the quality control unit has approved and documented such repackaging or relabeling.

(e) You must retest or reexamine any repackaged or relabeled dietary ingredients or dietary supplements. They must meet all specifications and

the quality control unit must approve or reject their release for distribution.

(f)(1) You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies; and

(2) You must examine, before packaging operations, packaging and labels for each batch of dietary ingredient or dietary supplement to ensure that the label and packaging conform to the master manufacturing record.

(g) The person that performs the requirements of this section must document at the time of performance that the requirements are performed including, but not limited to, documentation in the batch production record of:

(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 paragraph (b)(7) of this section;

(3) The conclusions you reached from retests conducted in accordance with paragraph (e) of this section; and

(4) Any material reviews and disposition decisions for packaging and labels.

(h) You must keep packaging and label operations records required under this section in accordance with § 111.125.

### § 111.74 What requirements apply to rejected components, dietary ingredients, dietary supplements, packaging, and labels?

You must 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.

9. Add subpart F to part 111 to read as follows:

## Subpart F—Holding and Distributing

Sec.

111.80 What requirements apply to holding components, dietary ingredients, dietary supplements, packaging, and labels?
111.82 What requirements apply to holding in-process material?
111.83 What requirements apply to holding reserve samples of components, dietary ingredients, and dietary supplements?
111.85 What requirements apply to returned dietary ingredients or dietary supplements?
111.90 What requirements apply to distributing dietary ingredients or dietary supplements?

## Subpart F—Holding and Distributing

### § 111.80 What requirements apply to holding components, dietary ingredients, dietary supplements, packaging, and labels?

(a) You must 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.

(b) You must hold packaging and labels under appropriate conditions of temperature, humidity, and light so that the quality of the packaging and labels are not affected.

(c) You must hold components, dietary ingredients, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary ingredients, dietary supplements, packaging, and labels.

### § 111.82 What requirements apply to holding in-process material?

(a) You must identify and hold in-process material under conditions that will protect them against mixup, contamination, and deterioration.

(b) You must hold in-process material under appropriate conditions of temperature, humidity, and light.

### § 111.83 What requirements apply to holding reserve samples of components, dietary ingredients, and dietary supplements?

(a) For any reserve samples of components or dietary ingredients you collect, you must hold such reserve samples in a manner that protects against contamination and deterioration.

(b) You must hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. This includes, but is not limited to:

(1) Holding the 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; and

(2) 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.

### § 111.85 What requirements apply to returned dietary ingredients or dietary supplements?

(a) You must identify and quarantine returned dietary ingredients or dietary supplements until the quality control unit conducts a material review and makes a disposition decision.

(b) You must not salvage returned dietary ingredients and 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.

(c) You must destroy or suitably dispose of the returned dietary ingredients or dietary supplements if such dietary ingredients or dietary supplements do not meet specifications for identity, purity, quality, strength, and composition, unless the quality control unit conducts a material review and makes a disposition decision to allow reprocessing.

(d) If the reason for a dietary ingredient or 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.

(e) You must establish and keep records for this section on the material review and disposition decision and any testing conducted to determine compliance with established specifications in the master manufacturing record for the type of dietary ingredient or dietary supplement that was returned.

(f) You must keep returned dietary ingredient and dietary supplement records in accordance with § 111.125.

### § 111.90 What requirements apply to distributing dietary ingredients or dietary supplements?

Distribution of dietary ingredients and dietary supplements must be under conditions that will protect the dietary ingredients and dietary supplements against contamination and deterioration.

10. Add subpart G to part 111 to read as follows:

## Subpart G—Consumer Complaints

### § 111.95 What requirements apply to consumer complaints?

(a) A qualified person must review all consumer complaints to determine whether the consumer complaint involves a possible failure of a dietary ingredient or 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 possible risk of illness or injury.

(b) Your quality control unit must review all consumer complaints involving the possible failure of a dietary ingredient or 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 possible risk of illness or injury, to determine whether there is a need to investigate the consumer complaint.

(c) Your quality control unit must investigate a consumer complaint when there is a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event.

(d) Your quality control unit's investigation of a consumer complaint must include the batch records associated with the dietary ingredient or dietary supplement involved in the consumer complaint. Your quality control unit must extend the investigation to other batches of dietary ingredients or dietary supplements that may have been associated with an adverse event.

(e) You must 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. The consumer complaint written record must include, but is not limited to, the following:

(1) The name and description of the dietary ingredient or dietary supplement;

(2) The batch or lot number of the dietary supplement, if available;

(3) The name of the complainant, if available;

(4) The nature of the complaint including how the consumer used the product;

(5) The reply to the complainant, if any; and

(6) Findings of the investigation and followup action taken when an investigation is performed.

(f)(1) The person who performs the requirements in accordance with this section must document at the time of performance that the requirement was performed.

(2) You must keep consumer complaint records in accordance with § 111.125.

11. Add subpart H to part 111 to read as follows:

## Subpart H—Records and Recordkeeping

### § 111.125 What requirements apply to recordkeeping?

(a) You must keep written records required by this part for 3 years beyond the date of manufacture of the last batch of dietary ingredients or dietary supplements associated with those records.

(b) Records required under this part 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. If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA. All electronic records must comply with part 11 of this chapter.

(c) You must have all records required under this part, or copies of such records, readily available during the retention period for authorized inspection and copying by FDA when requested.

12. Part 112 is added to read as follows:

## PART 112—RESTRICTIONS FOR SUBSTANCES USED IN DIETARY SUPPLEMENTS

### Subpart A—General Provisions [Reserved]

### Subpart B—New Dietary Ingredients [Reserved]

### Subpart C—Restricted Dietary Ingredients [Reserved]

**Authority:** 21 U.S.C. 321, 342, 343, 371.

Dated: January 29, 2003.

**Mark B. McClellan,**

*Commissioner of Food and Drugs.*

Dated: January 29, 2003.

**Tommy G. Thompson,**

*Secretary of Health and Human Services.*

[FR Doc. 03–5401 Filed 3–12–03; 11:30 am]

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# Part III

# Environmental Protection Agency

## 40 CFR 439

## Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category; Direct Final Rule and Proposed Rule

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 439**

**[FRL–7462–8]**

## Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category

**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking direct final action to amend certain provisions of the effluent guidelines for the Pharmaceutical Manufacturing Point Source Category, which were published on September 21, 1998 (63 FR 50424). First, EPA is clarifying the date on which a discharger subject to the New Source Performance Standards (NSPS) and the Pretreatment Standards for New Sources (PSNS) would be subject to effluent limitations and pretreatment standards established in the 1998 regulation. Second, this rule re-establishes a minimum concentration for the maximum monthly average $BOD_5$ limitation that EPA inadvertently omitted from the Best Practicable Control Technology (BPT) requirements in two subcategories of the 1998 regulation. Next, the amendments correct an error in EPA's pass-through analysis prepared in support of the 1998 rule and, as a result, deletes methyl Cellosolve (2-methoxyethanol) from the pretreatment standards in two subcategories and from Appendix A, Table 2, ''Surrogate Parameters for Indirect Dischargers.'' Finally, the Agency is making other non-substantive editorial and format changes such as removing redundancies, and adding definitions.

**DATES:** This rule is effective on June 11, 2003 without further notice, unless EPA receives adverse comment by May 12, 2003. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Please mail comments to the Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460 or submit them electronically to *http://www.epa.gov/edocket.* Send either to the Attention of Docket ID No. OW–2003–0007. See section I.C., of the **SUPPLEMENTARY INFORMATION** section for more information on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Dr. Frank Hund, EPA Office of Water by phone at (202)566–1027 or by e-mail at *hund.frank@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Regulated Entities*

Entities potentially regulated by this action include facilities of the following types that discharge pollutants directly or indirectly to U.S. waters.

| Category | Examples of regulated entities | SIC (NAICS) code |
|---|---|---|
| Industry ..... | Facilities that generate process wastewater from the manufacture of pharmaceutical products and/or pharmaceutical intermediates by fermentation, extraction, chemical synthesis and/or mixing, compounding and formulating. | 2833, R834, 2836 (2834–04, 2834–98). |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definitions and applicability criteria in §§ 439.1, 439.10, 439.20, 439.30, 439.40 and 439.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

*B. How Can I Get Copies of This Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OW–2003–0007. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Water Docket is (202) 566–2426. For access to docket materials, please call ahead to schedule an appointment. Every user is entitled to copy 100 pages before incurring a charge. The Docket may charge 15 cents a page for each page over the 100-page limit.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, ''EPA Dockets.'' You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

### II. Legal Authority

The U.S. Environmental Protection Agency is promulgating these regulations under the authority of 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

### III. Overview of Effluent Limitations Guidelines and Standards

Congress adopted the Clean Water Act (CWA) to ''restore and maintain the chemical, physical, and biological integrity of the Nation's waters'' (section 101(a), 33 U.S.C. 1251(a)). To achieve this goal, the CWA prohibits the discharge of pollutants into navigable waters except in compliance with the statute. The Clean Water Act confronts the problem of water pollution on a number of different fronts. Its primary reliance, however, is on establishing restrictions on the types and amounts of pollutants discharged from various industrial, commercial, and public sources of wastewater.

Congress recognized that regulating only those sources that discharge effluent directly into the nation's waters would not be sufficient to achieve the CWA's goals. Consequently, the CWA requires EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges for those who discharge wastewater indirectly through sewers flowing to publicly-owned treatment works (POTWs) (section 307(b) and (c), 33 U.S.C. 1317(b) and (c)). National pretreatment standards are established for those pollutants in wastewater from indirect dischargers which may pass through or interfere with POTW operations. Generally, pretreatment standards are designed to ensure that wastewater from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, POTWs are required to implement local pretreatment limits applicable to their industrial indirect dischargers to satisfy any local requirements (40 CFR 403.5).

Direct dischargers must comply with effluent limitations in National Pollutant Discharge Elimination System (NPDES) permits; indirect dischargers must comply with pretreatment standards. These limitations and standards are established by regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology.

On November 17, 1976, (41 FR 50676) EPA promulgated ''best practicable control technology currently available'' (BPT) effluent limitations guidelines for the Pharmaceutical Manufacturing Point Source Category. On October 27, 1983, (48 FR 49808) the Agency revised the BPT limitations and promulgated additional limitations covering the ''best available technology economically achievable'' (BAT) and pretreatment and new source standards for this point source category.

On September 21, 1998, (63 FR 50388) EPA again revised the effluent limitations guidelines and standards for the Pharmaceutical Manufacturing Point Source Category. We subsequently received comments from the regulated community and after our own analysis and review, we determined that several minor amendments which are discussed below were warranted.

## IV. Amendment to New Source Effective Dates

Section 306 of the Clean Water Act requires EPA to establish, and from time to time, revise standards of performance for categories of new sources which may discharge pollutants. Under the Act, point sources constructed to meet these NSPS may not be subject to more stringent standards during a statutorily prescribed period following construction of such source, generally 10 years. EPA first promulgated NSPS for the Pharmaceutical Manufacturing Point Source Category in 1983 when the Agency established effluent limitations guidelines and pretreatment standards for this category. When EPA promulgated revised limitations and standards, including NSPS, for the Pharmaceuticals Manufacturing Point Source Category in 1998, 40 CFR 439.15(c), 439.25(c), 439.35(c), and 439.45(c) provided for this protection period from more stringent standards. For example, paragraph (c) of § 439.15 states:

> Any new source subject to the provisions of this section that commenced discharging after November 21, 1988 and prior to November 20, 1998 must continue to achieve the standards specified in the *earlier version of this section* until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.13 and 439.14. (Emphasis supplied)

In order to remove any ambiguity about which regulations applied to dischargers constructing new facilities and commencing discharge after the 1983 regulation but before the effective date of the 1998 regulations, EPA is amending the regulation. EPA is amending paragraph (c) of each of the four sections cited above to state clearly that any new source that commenced discharging after November 21, 1988, and before November 20, 1998, must continue to achieve the standards specified for 40 CFR part 439 in the October 27, 1983, **Federal Register** (48 FR 49808) (which are contained in the 1988 edition of the CFR) until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1). Thereafter, the source must comply with the applicable effluent limitations specified in the September 21, 1998, regulation (63 FR 50388). The amendments substitute for the phrase ''earlier version'' a specific reference to the 1988 edition of 40 CFR part 439. This will remove any uncertainty about the standards with which a point source discharger must comply.

Section 307(c) of the CWA also requires EPA to promulgate pretreatment standards for new sources simultaneously with the promulgation of NSPS for a category of sources. When EPA promulgated the PSNS for the Pharmaceutical Manufacturing Point Source Category in 1998, PSNS in §§ 439.17, 439.27, 439.37, and 439.47 failed to specify when a source constructed before the date on which the new PSNS became effective would be subject to the more stringent standards. To correct this oversight, EPA is revising each of these four sections to read as follows:

> Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, which ever comes first, after which the source must achieve the same standards as specified in [insert the appropriate PSES section for the subpart].

## V. Amendment to BOD Minimum Limitation

When EPA issued regulations for the Pharmaceutical Manufacturing Point Source Category on October 27, 1983 (49 FR 49808), the best practicable control technology (BPT) regulation in §§ 439.22 and 439.42 provided for a minimum monthly average limitation for $BOD_5$, which was qualified by the following sentence: ''However, a plant shall not be required to attain a maximum 30-day average $BOD_5$ effluent limitation of less than the equivalent of 45 mg/l.'' EPA included this provision because dischargers with $BOD_5$ levels up to 100 mg/L in their raw wastewater could not achieve the required 90% reduction of $BOD_5$ using biological treatment, the technological basis for the limitation. Since biological treatment could not achieve the required reduction for such dischargers, EPA established a qualified provision for a minimum $BOD_5$ concentration in the 1983 regulation.

EPA inadvertently omitted this qualified provision of the $BOD_5$ limitations from the final rule published in 1998, and this language consequently has not been included in subsequent editions of 40 CFR part 439. Today EPA is correcting this omission by adding to §§ 439.22(a) and 439.42(a) the phrase: '' * * *, except that no facility shall be required to attain a monthly average limitation for $BOD_5$ that is less than the equivalent of 45 mg/L.''

## VI. Amendment To Delete Methyl Cellosolve From Pretreatment Standards

EPA is amending 40 CFR part 439 by deleting the pretreatment standards for methyl Cellosolve from §§ 439.16, 439.17, 439.36 and 439.37, and from Table 2 of Appendix A. In the 1998 regulation, EPA established pretreatment standards for methyl

Cellosolve and other pollutants which EPA's pass-through analysis concluded would pass through POTW treatment rather than be removed by POTW treatment. EPA based its determination on a chemical and engineering evaluation of which pollutants would not be susceptible to treatment in POTW biological treatment systems. EPA's pass-through analysis depended on a number of calculations, relying in part on a comparison of a parameter's Henry's Law Constant ($H_L$) with a threshold $H_L$ value.

In a letter to EPA dated November 28, 2000, the Pharmaceutical Research and Manufacturers of America (PhRMA) indicated that EPA had used an incorrect $H_L$ value for methyl Cellosolve in the pass-through analysis by assuming an $H_L$ value of $2.9 \times 10^{-3}$ atm/gmole/m$^3$. This was the same $H_L$ value that had been used for methyl Cellosolve by EPA's Office of Air Quality Planning and Standards (OAQPS) in establishing the Maximum Air Control Technology (MACT) standards for pharmaceutical manufacturers that were promulgated in 1998, and that had been developed concomitantly with revised pretreatment standards for 40 CFR part 439. The OAQPS, however, subsequently revised its $H_L$ value for methyl Cellosolve from $2.9 \times 10^{-3}$ to $3.3 \times 10^{-7}$ atm/gmole/m$^3$, based on a value reported by Johanson G. and Dynesius B. in ''Liquid/air partition coefficients of six commonly used glycol ethers,'' *British Journal of Industrial Medicine,* 1988, 45:561–564.

The determination of an incorrect $H_L$ constant was reinforced when EPA also considered the analytical technique required to measure low concentrations of methyl Cellosolve in wastewater. Analytical methods to measure volatile organic analytes (VOAs) utilize an inert gas purging technique to recover VOAs from a wastewater sample. But methyl Cellosolve does not purge efficiently and so must be analyzed using a direct injection technique. This fact offered additional evidence that EPA had used an inappropriate $H_L$ value for methyl Cellosolve in the earlier pass-through analysis of the pretreatment standards.

The revised $H_L$ for methyl Cellosolve ($3.3 \times 10^{-7}$ atm/gmole/m$^3$) is well below the threshold $H_L$ value ($1 \times 10^{-5}$ atm/gmole/m$^3$) that EPA used to classify a compound as a volatile organic compound (VOC) for purposes of the Agency's pass-through analysis. Thus, EPA relied on an inappropriate $H_L$ value for methyl Cellosolve in the pass-through analysis for the 1998 rule. This caused this compound to be identified as a VOC, which the Agency's pass-through analysis determined would pass through a POTW's treatment. When EPA used the corrected lower $H_L$ value and found that methyl Cellosolve was not a VOC, the Agency's pass-through analysis determined that this compound would not pass through a POTW's treatment.

## VII. Additional Edits to 40 CFR Part 439

Today's rule also includes non-substantive edits and format changes to the rule promulgated in 1998 in order to shorten and clarify 40 CFR part 439. The ''Authority'' citation was shortened to conform with current guidance from the Federal Register Office. The text from § 439.4 was merged into § 439.2 and the heading of § 439.2 was revised to read: ''General monitoring requirements.'' Section 439.4 was re-designated under a new heading ''General limitation or standard for pH'' and the term ''Subcategory'' was removed from the heading of all subparts. EPA has also added definitions of ''Maximum daily'' and ''Maximum monthly average'' to § 439.1. These definitions are similar to those used in other effluent limitations guidelines and pretreatment standards regulations and reflect the definitions used to promulgate the limits in the existing 40 CFR part 439. Finally, the initial phrase, ''The term * * *'' was removed from all definitions, column headings and titles of all tables. Corresponding text referencing these headings and titles was also revised.

## VIII. Rationale for Direct Final Rule

EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comment. The changes here will facilitate the implementation of part 439 and will not affect environmental impacts or compliance costs. They merely clarify applicable dates, correct an inadvertent error and omission, and make other non-substantive edits. However, in the ''Proposed Rules'' section of today's **Federal Register,** we are publishing a separate document that will serve as the proposal to amend part 439, as described herein, if adverse comments are filed. This rule will be effective on June 11, 2003 without further notice, unless we receive adverse comment by May 12, 2003. If EPA receives adverse comment on one or more distinct amendments, paragraphs, or sections of this rulemaking, we will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn due to adverse comment. Any distinct amendment, paragraph, or section of today's rulemaking for which we do not receive adverse comment will become effective on the date set out above, notwithstanding any adverse comment on any other distinct amendment, paragraph, or section of today's rule. We will address all adverse public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

## IX. Statutory and Executive Order Reviews

### *A. Executive Order 12866: Regulatory Planning and Review*

Under Executive Order 12866 (58 FR 51735, (October 4, 1993)), the Agency must determine whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

### *B. Paperwork Reduction Act*

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology

and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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.

*C. Regulatory Flexibility Act*

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

For purposes of assessing the impact of today's final rule on small entities, a small entity is defined as (1) a small business with gross revenue under $6 million (based on Small Business Administration size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. As explained above, the change to the PSNS sections of the regulation merely removes any ambiguity about the applicability of the earlier 1983 pretreatment standards during the 10-year protection period prior to November 20, 1998, and makes them consistent with the latest NSPS sections. The PSNS revision does not establish any new requirements with respect to those subject to the regulation. The other changes similarly would have either no effect on the regulated entities, or at most an inconsequential effect. The deletion of methyl Cellosolve would reduce the economic impacts of the regulation on those entities, including small entities, subject to pretreatment standards in the two subparts which currently contain methyl Cellosolve as a regulated parameter. In addition, as noted above, the revision to re-establish the minimum concentration for $BOD_5$ would correct an earlier inadvertent omission and reflect the requirements of existing discharge permits.

*D. Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local and tribal governments, in the aggregate, or the private sector in any one year. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. Thus, today's rule is not subject to the requirements of sections 202 and 205 of UMRA.

For the same reason, EPA has determined that this final rule contains no regulatory requirements that might significantly affect small governments. The final rule does not uniquely affect small governments because small and large governments are affected in the same way. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

*E. Executive Order 13132: Federalism*

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations 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.''

This final rule does not have federalism implications. It 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, as specified in Executive Order 13132. Today's rule amends effluent limitations and pretreatment standards which impose requirements that apply to facilities when they discharge wastewater or introduce wastewater to a POTW. It merely clarifies applicable dates, corrects an inadvertent error, and omission, and makes other non-substantive edits. EPA has determined that there are no pharmaceutical facilities owned and/or operated by State or local governments that would be subject to today's rule. Further, the rule would only incidentally affect State and local governments in their capacity as implementers of CWA NPDES permitting programs. Thus, Executive Order 13132 does not apply to this rule.

*F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have substantial direct effects on one or more Indian tribes, on the relationship between Federal government and Indian tribes or on the distribution of power and responsibilities between the Federal government and Indian tribes.

This final rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between this Federal government and Indian tribes or on the distribution of power and responsibilities between the Federal government and Indian tribes. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. EPA has not identified any pharmaceutical facilities covered by today's rule that are owned and/or operated by Indian tribal governments. No Indian tribes are responsible for implementing the CWA NPDES permitting program. Thus, Executive Order 13175 does not apply to this rule.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined under Executive Order 12866. Further, this rule does not concern an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children.

*H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use*

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355; May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

*J. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the publication of the rule in **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective June 11, 2003.

**List of Subjects in 40 CFR Part 439**

Environmental protection, Drugs, Reporting and recordingkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: February 28, 2003.

**Christine Todd Whitman,**

*Administrator.*

For reasons set out in the preamble, part 439, title 40, chapter I of the Code of Federal Regulations is amended as follows:

## PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

1. The authority citation for part 439 is revised to read as follows:

**Authority:** 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

2. Section 439.1 is amended by revising paragraphs (b) through (n) and adding paragraphs (o) and (p) to read as follows:

### § 439.1 General definitions.

* * * * *

(b) *Bench-scale operation* means the laboratory testing of materials, methods, or processes on a small scale, such as on a laboratory worktable.

(c) *Cyanide (T)* means the parameter total cyanide.

(d) *In-plant monitoring point* means a location within a plant, where an individual process effluent can be exclusively monitored before it is diluted or mixed with other process wastewaters en route to the end-of-pipe.

(e) *Maximum daily* means the highest allowable discharge of wastewater pollutants during a calender day or any 24 hour period that reasonably represents a calender day for purposes of sampling.

(f) *Maximum monthly average* means the highest allowable average of daily discharges of wastewater pollutants over a calendar month, and is calculated as the sum of all daily values measured during a calendar month divided by the number of daily values measured during that month.

(g) *mg/L* means milligrams per liter or parts per million (ppm)

(h) *Minimum level* means the level at which an analytical system gives recognizable signals and an acceptable calibration point.

(i) *Nitrification capability* means the capability of a POTW treatment system to oxidize ammonia or ammonium salts initially to nitrites (via *Nitrosomonas* bacteria) and subsequently to nitrates (via *Nitrobacter* bacteria). Criteria for determining the nitrification capability of a POTW treatment system are: bioassays confirming the presence of nitrifying bacteria; and analyses of the nitrogen balance demonstrating a reduction in the concentration of ammonia or ammonium salts and an

increase in the concentrations of nitrites and nitrates.

(j) *Non-detect (ND)* means a concentration value below the minimum level that can be reliably measured by the analytical method.

(k) *Pilot-scale operation* means processing equipment being operated at an intermediate stage between laboratory-scale and full-scale operation for the purpose of developing a new product or manufacturing process.

(l) *POTW* means publicly owned treatment works (40 CFR 403.3).

(m) *Process wastewater,* as defined at 40 CFR 122.2 and for the purposes of this part, does not include the following:

(1) Trimethyl silanol, any active anti-microbial materials, process wastewater from imperfect fermentation batches, and process area spills. Discharges containing such materials are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (*e.g.*, contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(n) *Non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor ''toxic'' pollutants (40 CFR 401.15).

(o) *Surrogate pollutant* means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in Appendix A of this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(p) *Xylenes* means a combination of the three isomers: o-xylene, m-xylene, and p-xylene.

3. Section 439.2 is revised to read as follows:

**§ 439.2 General monitoring requirements.**

(a) Permit compliance monitoring is required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part, a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with a recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and measurement of a non-detect value for each regulated pollutant or its surrogate. Permits must specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

(b) Unless noted otherwise, self-monitoring will be conducted at the point where the final effluent is discharged.

4. Section 439.4 is revised to read as follows:

**§ 439.4 General limitation or standard for pH.**

The pH must remain within the range 6.0 to 9.0 in any discharge subject to BPT, BCT or NSPS limitations or standards in this part.

5. Revise the heading of subpart A to read as follows:

## Subpart A—Fermentation Products

6. Section 439.11 is revised to read as follows:

**§ 439.11 Special definitions.**

For the purpose of this subpart:

(a) *Fermentation* means process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product.

(b) *Product* means pharmaceutical products derived from fermentation processes.

7. Section 439.12 is amended by revising paragraphs (a) introductory text, and (b) through (e) to read as follows:

**§ 439.12 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).**

* * * * *

(a) The maximum monthly average limitation for $BOD_5$, expressed as mass loading (lbs., kg) per day, must reflect not less than 90 percent reduction in the long-term average daily $BOD_5$ load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0.

* * * * *

(b) The maximum monthly average limitation for TSS, expressed as mass loading (lbs., kg) per day, must be calculated as 1.7 times the $BOD_5$ limitation determined in paragraph (a) of this section.

(c) Except as provided in paragraph (d) of this section, the limitations for COD are as follows:

EFFLUENT LIMITATIONS (BPT)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| COD ..... | 1675 | 856 |

[1] mg/L (ppm).

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then the monthly average limitation for COD corresponding to the lower concentration value must be applied.

(e) The effluent limitations for cyanide are as follows:

EFFLUENT LIMITATIONS (BPT)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| Cyanide (T) ..... | 33.5 | 9.4 |

[1] mg/L (ppm).

* * * * *

8. Section 439.14 is revised to read as follows:

**§ 439.14 Effluent limitations attainable by the application of best available technology economically achievable (BAT).**

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT:

EFFLUENT LIMITATIONS (BAT)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| Ammonia (as N) | 84.1 | 29.4 |
| Acetone | 0.5 | 0.2 |
| 4-methyl-2-pentanone | 0.5 | 0.2 |
| Isobutyraldehyde | 1.2 | 0.5 |
| n-Amyl acetate | 1.3 | 0.5 |
| n-Butyl acetate | 1.3 | 0.5 |
| Ethyl acetate | 1.3 | 0.5 |
| Isopropyl acetate | 1.3 | 0.5 |
| Methyl formate | 1.3 | 0.5 |
| Amyl alcohol | 10.0 | 4.1 |
| Ethanol | 10.0 | 4.1 |
| Isopropanol | 3.9 | 1.6 |
| Methanol | 10.0 | 4.1 |
| Methyl Cellosolve | 100.0 | 40.6 |
| Dimethyl sulfoxide | 91.5 | 37.5 |
| Triethyl amine | 250.0 | 102.0 |
| Phenol | 0.05 | 0.02 |
| Benzene | 0.05 | 0.02 |
| Toluene | 0.06 | 0.02 |
| Xylenes | 0.03 | 0.01 |
| n-Hexane | 0.03 | 0.02 |
| n-Heptane | 0.05 | 0.02 |
| Methylene chloride | 0.9 | 0.3 |
| Chloroform | 0.02 | 0.13 |
| 1,2-dichloroethane | 0.4 | 0.1 |
| Chlorobenzene | 0.15 | 0.06 |
| o-Dichlorobenzene | 0.15 | 0.06 |
| Tetrahydrofuran | 8.4 | 2.6 |
| Isopropyl ether | 8.4 | 2.6 |
| Diethyl amine | 250.0 | 102.0 |
| Acetonitrile | 25.0 | 10.2 |

[1] mg/L (ppm).

(b) The limitations for COD are the same as specified in § 439.12(c) and (d).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

9. Section 439.15 is revised to read as follows:

**§ 439.15 New source performance standards (NSPS).**

(a) Any new source subject to this subpart must achieve the following standards:

PERFORMANCE STANDARDS (NSPS)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| $BOD_5$ | 267 | 111 |
| TSS | 472 | 166 |
| COD | 1675 | 856 |
| Ammonia (as N) | 84.1 | 29.4 |
| Acetone | 0.5 | 0.2 |
| 4-methyl-2-pentanone | 0.5 | 0.2 |
| Isobutyraldehyde | 1.2 | 0.5 |
| n-Amyl acetate | 1.3 | 0.5 |
| n-Butyl acetate | 1.3 | 0.5 |
| Ethyl acetate | 1.3 | 0.5 |
| Isopropyl acetate | 1.3 | 0.5 |
| Methyl formate | 1.3 | 0.5 |
| Amyl alcohol | 10.0 | 4.1 |
| Ethanol | 10.0 | 4.1 |

PERFORMANCE STANDARDS (NSPS)—Continued

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| Isopropanol | 3.9 | 1.6 |
| Methanol | 10.0 | 4.1 |
| Methyl Cellosolve | 100.0 | 40.6 |
| Dimethyl sulfoxide | 91.5 | 37.5 |
| Triethyl amine | 250.0 | 102.0 |
| Phenol | 0.05 | 0.02 |
| Benzene | 0.05 | 0.02 |
| Toluene | 0.06 | 0.02 |
| Xylenes | 0.03 | 0.01 |
| n-Hexane | 0.03 | 0.02 |
| n-Heptane | 0.05 | 0.02 |
| Methylene chloride | 0.9 | 0.3 |
| Chloroform | 0.02 | 0.13 |
| 1,2-dichloroethane | 0.4 | 0.1 |
| Chlorobenzene | 0.15 | 0.06 |
| o-Dichlorobenzene | 0.15 | 0.06 |
| Tetrahydrofuran | 8.4 | 2.6 |
| Isopropyl ether | 8.4 | 2.6 |
| Diethyl amine | 250.0 | 102.0 |
| Acetonitrile | 25.0 | 10.2 |

[1] mg/L (ppm)

(b) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.13 and 439.14.

10. Section 439.16 is revised to read as follows:

**§ 439.16 Preatment standards for existing sources (PSES).**

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue achieving the standards for cyanide specified in paragraph (c) of this section and must achieve the following standards by September 21, 2001:

PRETREATMENT STANDARDS (PSES)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| Ammonia (as N) [2] | 84.1 | 29.4 |
| Acetone | 20.7 | 8.2 |
| 4-methyl-2-pentanone | 20.7 | 8.2 |
| Isobutyraldehyde | 20.7 | 8.2 |
| n-Amyl acetate | 20.7 | 8.2 |
| n-Butyl acetate | 20.7 | 8.2 |
| Ethyl acetate | 20.7 | 8.2 |
| Isopropyl acetate | 20.7 | 8.2 |
| Methyl formate | 20.7 | 8.2 |

PRETREATMENT STANDARDS (PSES)—Continued

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| Isopropyl ether | 20.7 | 8.2 |
| Tetrahydrofuran | 9.2 | 3.4 |
| Benzene | 3.0 | 0.7 |
| Toluene | 0.3 | 0.2 |
| Xylenes | 3.0 | 0.7 |
| n-Heptane | 3.0 | 0.7 |
| n-Hexane | 3.0 | 0.7 |
| Methylene chloride | 3.0 | 0.7 |
| Chloroform | 0.1 | 0.03 |
| 1,2-dichloroethane | 20.7 | 8.2 |
| Chlorobenzene | 3.0 | 0.7 |
| *o*-Dichlorobenzene | 20.7 | 8.2 |
| Diethyl amine | 255.0 | 100.0 |
| Triethyl amine | 255.0 | 100.0 |

[1] mg/L (ppm)

[2] Not applicable to sources that discharge to a POTW with nitrification capability.

(b) Sources that discharge to a POTW with nitrification capability (defined at § 439.1(i)) are not required to achieve the pretreatment standard for ammonia (as N).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

11. Section 439.17 is revised to read as follows:

**§ 439.17 Pretreatment standards for new sources (PSNS).**

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.16.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.16.

12. Revise the heading of subpart B to read as follows:

## Subpart B—Extraction Products

13. Section 439.21 is revised to read as follows:

**§ 439.21 Special definitions.**

For the purpose of this subpart:

(a) *Extraction* means process operations that derive pharmaceutically active ingredients from natural sources

such as plant roots and leaves, animal glands, and parasitic fungi by chemical and physical extraction.

(b) *Product* means any substance manufactured by an extraction process, including blood fractions, vaccines, serums, animal bile derivatives, endocrine products and medicinal products such as alkaloids that are isolated from botanical drugs and herbs.

14. Section 439.22 is amended by revising paragraphs (a) introductory text and (b) through (d) to read as follows:

**§ 439.22 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).**

* * * * *

(a) The limitation for $BOD_5$ is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for $BOD_5$ that is less than the equivalent of 45 mg/L.

* * * * *

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) Except for the provisions in paragraph (d) of this section, the limitations for COD are as follows:

EFFLUENT LIMITATIONS (BPT)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| COD | 228 | 86 |

[1] mg/L (ppm)

(d) If the maximum monthly average COD concentration in paragraph (c) of this section is higher than a concentration value reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, then a monthly average limitation for COD corresponding to the lower concentration value must be applied.

15. Section 439.25 is revised to read as follows:

**§ 439.25 New source performance standards (NSPS).**

(a) Any new source subject to this subpart must achieve the following standards:

PERFORMANCE STANDARDS (NSPS)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| $BOD_5$ | 35 | 18 |
| TSS | 58 | 31 |

PERFORMANCE STANDARDS (NSPS)—Continued

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| COD | 228 | 86 |

[1] mg/L (ppm)

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in §§ 439.23 and 439.24.

16. Section 439.26 is revised to read as follows:

**§ 439.26 Pretreatment standards for existing sources (PSES).**

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following standards by September 21, 2001:

PRETREATMENT STANDARDS (PSES)

| Regulated parameter | Maximum daily [1] | Maximum monthly average [1] |
|---|---|---|
| Acetone | 20.7 | 8.2 |
| n-Amyl acetate | 20.7 | 8.2 |
| Ethyl acetate | 20.7 | 8.2 |
| Isopropyl acetate | 20.7 | 8.2 |
| Methylene chloride | 3.0 | 0.7 |

[1] mg/L (ppm).

17. Section 439.27 is revised to read as follows:

**§ 439.27 Pretreatment standards for new sources (PSNS).**

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.26.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.26.

18. Revise the heading of Subpart C to read as follows:

## Subpart C—Chemical Synthesis Products

19. Section 439.31 is revised, including the section heading, to read as follows:

**§ 439.31 Special definitions.**

For the purpose of this subpart:

(a) *Chemical synthesis* means using one or a series of chemical reactions in the manufacturing process of a specified product.

(b) *Product* means any pharmaceutical product manufactured by chemical synthesis.

20. Section 439.32 is amended by revising paragraphs (a) through (d) and removing paragraphs (e) through (g) to read as follows:

**§ 439.32 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).**

* * * * *

(a)The limitation for $BOD_5$ is the same as specified in § 439.12(a).

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) The limitations for COD are the same as specified in § 439.12(c) and (d).

(d) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

* * * * *

21. Section 439.34 is revised to read as follows:

**§ 439.34 Effluent limitations attainable by the application of best available technology economically achievable (BAT).**

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT:

(a) The limitations are the same as specified in § 439.14(a).

(b) The limitations for COD are the same as specified in § 439.12(c) and (d).

(c) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

22. Section 439.35 is revised to read as follows:

**§ 439.35 New source performance standards (NSPS).**

(a) Any new source subject to this subpart must achieve the same standards as specified in § 439.15(a).

(b) The limitations for cyanide are the same as specified in § 439.12(e), (f) and (g).

(c) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.33 and § 439.34.

23. Section 439.36 is revised to read as follows:

**§ 439.36 Pretreatment standards for existing sources (PSES).**

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must continue achieving the standards for cyanide specified in paragraph (b) of this section and must achieve the standards specified in § 439.16(a) by September 21, 2001.

(a) Sources that discharge to a POTW with nitrification capability (defined at § 439.1(i)) are not required to achieve the standards for ammonia (as N).

(b) The standards for cyanide are the same as specified in § 439.12(e), (f) and (g).

24. Section 439.37 is revised to read as follows:

**§ 439.37 Pretreatment standards for new sources (PSNS).**

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.36.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.36.

25. Revise the heading of Subpart D to read as follows:

## Subpart D—Mixing/Compounding and Formulation

26. Section 439.41 is revised to read as follows:

**§ 439.41 Special definitions.**

For the purpose of this subpart:

(a) *Mixing, compounding, and formulating operations* means processes that put pharmaceutical products in dosage forms.

(b) *Product* means any pharmaceutical product manufactured by blending, mixing, compounding, and formulating pharmaceutical ingredients. The term includes pharmaceutical preparations for both human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions.

27. Section 439.42 is amended by revising paragraphs (a) through (c) and removing paragraph (d) to read as follows:

**§ 439.42 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).**

* * * * *

(a) The limitation for $BOD_5$ is the same as specified in § 439.12(a). No facility shall be required to attain a monthly average limitation for $BOD_5$ that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) The limitations for COD are the same as specified in § 439.22(c) and (d).

* * * * *

28. Section 439.44 is revised to read as follows:

**§ 439.44 Effluent limitations attainable by the application of best available technology economically achievable (BAT).**

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the application of BAT: The limitations for COD are the same as specified in § 439.22(c) and (d).

29. Section 439.45 is revised to read as follows:

**§ 439.45 New source performance standards (NSPS).**

(a) Any new source subject to this subpart must achieve the same standards as specified in § 439.25(a).

(b) Any new source subject to the provisions of this section that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the standards specified for this section in the 1988 edition of 40 CFR part 439, until the expiration of the applicable time period specified in 40 CFR 122.29(d)(1), after which the source must achieve the standards specified in § 439.43 and § 439.44.

30. Section 439.46 is revised to read as follows:

**§ 439.46 Pretreatment standards for existing sources (PSES).**

Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart must achieve the following standards by September 21, 2001:

PRETREATMENT STANDARDS (PSES)

| Regulated parameter | Maximum daily[1] | Maximum monthly average[1] |
|---|---|---|
| Acetone | 20.7 | 8.2 |
| n-Amyl acetate | 20.7 | 8.2 |
| Ethyl acetate | 20.7 | 8.2 |
| Isopropyl acetate | 20.7 | 8.2 |
| Methylene chloride | 3.0 | 0.7 |

[1] mg/L (ppm).

31. Section 439.47 is revised to read as follows:

**§ 439.47 Pretreatment standards for new sources (PSNS).**

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharge on November 20, 1998, or thereafter must achieve the same standards as specified in § 439.46.

(b) Except as provided in 40 CFR 403.7, any new source subject to this subpart that commenced discharging after November 21, 1988, and prior to November 20, 1998, must continue to achieve the pretreatment standards specified for this section in the 1988 edition of 40 CFR part 439 during a ten-year period beginning on the date the source commenced discharge, or during the period of depreciation or amortization of the facility, whichever comes first, after which the source must achieve the same standards as specified in § 439.46.

32. Revise the heading of subpart E to read as follows:

## Subpart E—Research

33. Section 439.51 is revised to read as follows:

**§ 439.51 Special definitions.**

For the purpose of this subpart, *product* means products or services resulting from research and product development activities.

34. Section 439.52 is amended by revising paragraphs (a) through (d) to read as follows:

**§ 439.52 Effluent limitations attainable by the application of the best practicable control technology currently available (BPT).**

* * * * *

(a) The limitation for $BOD_5$ is the same as specified in § 439.12(a). No

facility shall be required to attain a monthly average limitation for $BOD_5$ that is less than the equivalent of 45 mg/L.

(b) The limitation for TSS is the same as specified in § 439.12(b).

(c) The maximum monthly average limitation for COD, expressed as mass loading (lbs, kg) per day, must reflect not less than 74 percent reduction in the long-term average daily COD load of the raw (untreated) process wastewater, multiplied by a variability factor of 2.2. No facility shall be required to attain a limitation for COD that is less than the equivalent of 220 mg/L.

(d) The long-term average daily $BOD_5$ or COD mass loading of the raw process wastewater (*i.e.*, the base number to which the percent reduction is applied) is defined as the average daily $BOD_5$ or COD load during any calendar month, over 12 consecutive months within the most recent 36 months.

(1) To assure equity in the determination of NPDES permit limitations regulating discharges subject to this subpart, calculation of the long-term average daily $BOD_5$ or COD load in the influent to the wastewater treatment system must exclude any portion of the load associated with solvents, except for residual amounts of solvents remaining after the practices of recovery and/or separate disposal or reuse. Residual amounts of these substances may be included in the calculation of the average influent $BOD_5$ or COD loading.

(2) The practices of recovery, and/or separate disposal or reuse include: recovery of solvents from wastestreams; and incineration of concentrated solvent wastestreams (including tar still bottoms). This regulation does not prohibit the inclusion of such wastes in raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining NPDES permit limitations. The effluent limitation for $BOD_5$ or COD may be achieved by any of several, or a combination, of these practices.

* * * * *

35. Table 2 of Appendix A is revised to read as follows:

## Appendix A to Part 439—Tables

* * * * *

TABLE 2.—SURROGATE PARAMETERS FOR INDIRECT DISCHARGERS (UTILIZING STEAM STRIPPING TREATMENT TECHNOLOGY)

| Regulated parameters | Treatability class |
|---|---|
| Benzene<br>Toluene [1]<br>Xylenes<br>n-Heptane<br>Chloroform [1]<br>Methylene chloride [1]<br>Chlorobenzene | High strippability. |
| Ammonia (aqueous)<br>Diethyl amine<br>Triethyl amine<br>Acetone [1]<br>4-methyl-2-pentanone<br>n-Amyl acetate<br>n-Butyl acetate<br>Ethyl acetate<br>Isopropyl acetate<br>Methyl formate<br>Isopropyl ether<br>Tetrahydrofuran [1]<br>1,2-dichloroethane<br>o-Dichlorobenzene | Medium strippability. |

[1] These parameters may be used as a surrogate to represent other parameters in the same treatability class.

[FR Doc. 03–5716 Filed 3–12–03; 8:45 am]

BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 439**

**[FRL–7462–7]**

## Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category; Proposed Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to amend certain provisions of the effluent guidelines for the Pharmaceutical Manufacturing Point Source Category, which were published on September 21, 1998 (63 FR 50424). First, EPA is clarifying the date on which a discharger subject to the New Source Performance Standards (NSPS) and the Pretreatment Standards for New Sources (PSNS) would be subject to effluent limitations and pretreatment standards established in the 1998 regulation. Second, this rule re-establishes a minimum concentration for the maximum monthly average $BOD_5$ limitation that EPA inadvertently omitted from the Best Practicable Control Technology (BPT) requirements in two subcategories of the 1998 regulation. Next, the amendments correct an error in EPA's pass-through analysis prepared in support of the 1998 rule and, as a result, methyl Cellosolve (2-methoxyethanol) from the pretreatment standards in two subcategories and from Appendix A, Table 2, ''Surrogate Parameters for Indirect Dischargers.'' Finally, the Agency is making other non-substantive editorial and format changes such as removing redundancies, and adding definitions.

**DATES:** Comments must be received by May 12, 2003. Comments postmarked after this date may not be considered.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Please mail comments to the Water Docket, Environmental Protection Agency, Mailcode: 4101T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460 or submit them electronically to *http://www.epa.gov/edocket.* Send either to the Attention of Docket ID No. OW–2003–0007. See section I.C. of the **SUPPLEMENTARY INFORMATION** section for more information on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Dr. Frank Hund, U.S. EPA Office of Water by phone at (202) 566–1027 or by e-mail at *hund.frank@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Regulated Entities*

Entities potentially regulated by this action include facilities of the following types that discharge pollutants directly or indirectly to U.S. waters.

| Category | Examples of regulated entities | SIC (NAICS) code |
|---|---|---|
| Industry | Facilities that generate process wastewater from the manufacture of pharmaceutical products and/or pharmaceutical intermediates by fermentation, extraction, chemical synthesis and/or mixing, compounding and formulating. | 2833, R834, 2836 (2834–04, 2834–98). |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definitions and applicability criteria in §§ 439.10, 439.20, 439.30, 439.40 and 439.50 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

*B. How Can I Get Copies of This Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OW–2003–0007. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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 Water Docket is (202) 566–2426. For access to docket materials, please call ahead to schedule an appointment. Every user is entitled to copy 100 pages before incurring a charge. The Docket may charge 15 cents a page for each page over the 100-page limit.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''Federal Register'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, ''EPA Dockets.'' You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as confidential business information (CBI) and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

*C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. Please submit with your comments any references cited in your comments. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments; however, late comments may be considered if time permits. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in section I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD–ROM you submit, and in any cover letter accompanying the disk or CD–ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket,* and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select ''Information Sources,'' ''Dockets,'' and ''EPA Dockets.'' Once in the system, select ''search,'' and then key in Docket ID No. OW–2003–0007. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to *OW–Docket@epa.gov,* Attention Docket ID No. OW–2003–0007. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD–ROM.* You may submit comments on a disk or CD–ROM that you mail to the mailing address identified in section 1.C.2. These electronic submissions will be accepted in Word Perfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send an original and three (3) copies of your comments to the Water Docket, Environmental Protection Agency, Mail Code 4101T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention Docket ID No. OW–2003–0007.

3. *By Hand Delivery or Courier.* Deliver your comments to: Water Docket, EPA Docket Center, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC, Attention Docket ID No. OW–2003–0007. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.B.1.

*D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send information identified as CBI by mail only to the following address: Office of Science and Technology, Mail Code 4303T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Attention: Frank Hund, Docket ID No. OW–2003–0007.

You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD–ROM, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD–ROM, mark the outside of the disk or CD–ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

## II. Discussion of Direct Final Rulemaking

In the ''Rules and Regulations'' section of today's **Federal Register**, EPA is promulgating these revisions as a direct final rule without prior proposal because we view them as noncontroversial revisions and anticipate no adverse comment. We have explained our reasons for these revisions in the preamble to the direct final rule. If we receive no adverse comment, we will not take further

action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule or portions thereof, and the direct final rule or portions thereof will not take effect. We will address all public comments in a subsequent final rule based on this action. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

## III. Related Acts of Congress, Executive Orders, and Agency Initiatives

For the various statutes and Executive Orders that require findings for rulemaking, EPA incorporates the findings from the direct final rule into this companion proposal for the purpose of providing public notice and opportunity for comment.

## List of Subjects in 40 CFR Part 439

Environmental protection, Drugs, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: February 28, 2003.

**Christine Todd Whitman,**

*Administrator.*

[FR Doc. 03–5715 Filed 3–12–03; 8:45 am]

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Federal Register

Thursday,
March 13, 2003

# Part IV

# The President

## Memorandum of March 11, 2003—Designation of Officers of the Office of Personnel Management to Act as Director of the Office of Personnel Management

Federal Register
Vol. 68, No. 49
Thursday, March 13, 2003

# Presidential Documents

**Title 3—**

## The President

**Memorandum of March 11, 2003**

## Designation of Officers of the Office of Personnel Management to Act as Director of the Office of Personnel Management

**Memorandum for the Director of the Office of Personnel Management**

By the authority vested in me as President under the Constitution and laws of the United States of America and pursuant to the Federal Vacancies Reform Act of 1998, 5 U.S.C. 345 *et seq.*, I hereby order that:

**Section 1.** *Order of Succession.*

During any period when the Director of the Office of Personnel Management (Director), or the Deputy Director of the Office of Personnel Management, has died, resigned, or otherwise become unable to perform the functions and duties of the office of Director, the following officers of the Office of Personnel Management, in the order listed, shall perform the functions and duties of the office of Director, if they are eligible to act as Director under the provisions of the Federal Vacancies Reform Act of 1998, until such time as at least one of the officers mentioned above is able to perform the functions and duties of the office of Director:

Chief of Staff;

General Counsel;

Associate Director, Management and Chief Financial Officer;

Associate Director, Human Resources Policy;

Associate Director, Human Resources Products and Services;

Associate Director, Human Capital Leadership and Merit Systems Accountability;

Deputy Associate Director, Center for Investigations Services;

Director, Office of Congressional Relations;

Director, Office of Communications;

Senior Advisor, Homeland Security; and

Senior Advisor, Learning and Knowledge Management.

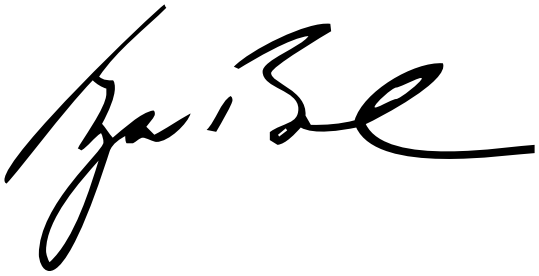
**Sec. 2.** *Exceptions.*

(a) No individual who is serving in an office listed in section 1 in an acting capacity, by virtue of so serving, shall act as Director pursuant to this memorandum.

(b) Notwithstanding the provisions of this memorandum, the President retains discretion, to the extent permitted by the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345–3349d, to depart from this memorandum in designating an acting Director.

**Sec. 3.** *Publication.*

You are authorized and directed to publish this memorandum in the **Federal Register.**



THE WHITE HOUSE,
*Washington, March 11, 2003.*

[FR Doc. 03–6255
Filed 3–12–03; 8:45 am]
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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 MARCH 13, 2003

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Alaska; fisheries of Exclusive Economic Zone—
Pollock; published 2-11-03

**LIBRARY OF CONGRESS**
National Film Preservation Board; National Film Registry; published 3-13-03

**VETERANS AFFAIRS DEPARTMENT**
Medical benefits:
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Allowance for drug prescriptions to be filled by non-VA pharmacies in state homes under VA contracts; published 3-13-03

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**Commodity Credit Corporation**
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Conservation Security Program; comments due by 3-20-03; published 2-18-03 [FR 03-03782]

**AGRICULTURE DEPARTMENT**
**Natural Resources Conservation Service**
Loan and purchase programs:
Conservation Security Program; comments due by 3-20-03; published 2-18-03 [FR 03-03782]

**AGRICULTURE DEPARTMENT**
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Civil rights discrimination complaints; adjudication; comments due by 3-17-03; published 2-14-03 [FR 03-03565]

**COMMERCE DEPARTMENT**
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**ENVIRONMENTAL PROTECTION AGENCY**
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Chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills; comments due by 3-20-03; published 2-18-03 [FR 03-03701]

**ENVIRONMENTAL PROTECTION AGENCY**
Air pollutants, hazardous; national emission standards:
Chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills; comments due by 3-20-03; published 2-18-03 [FR 03-03702]

**ENVIRONMENTAL PROTECTION AGENCY**
Air quality implementation plans; approval and promulgation; various States:
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**ENVIRONMENTAL PROTECTION AGENCY**
Air quality implementation plans; approval and promulgation; various States:
California; comments due by 3-17-03; published 2-13-03 [FR 03-03417]

**ENVIRONMENTAL PROTECTION AGENCY**
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Rhode Island; comments due by 3-17-03; published 2-14-03 [FR 03-03698]

**FEDERAL COMMUNICATIONS COMMISSION**
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**HEALTH AND HUMAN SERVICES DEPARTMENT**
**Food and Drug Administration**
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**PERSONNEL MANAGEMENT OFFICE**
Employee responsibilities and conduct; comments due by 3-17-03; published 1-15-03 [FR 03-00818]

**PERSONNEL MANAGEMENT OFFICE**
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**SECURITIES AND EXCHANGE COMMISSION**
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**TRANSPORTATION DEPARTMENT**

**Federal Aviation Administration**

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**VETERANS AFFAIRS DEPARTMENT**

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## LIST OF PUBLIC LAWS

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**H.R. 395/P.L. 108–10**

Do-Not-Call Implementation Act (Mar. 11, 2003; 117 Stat. 557)

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